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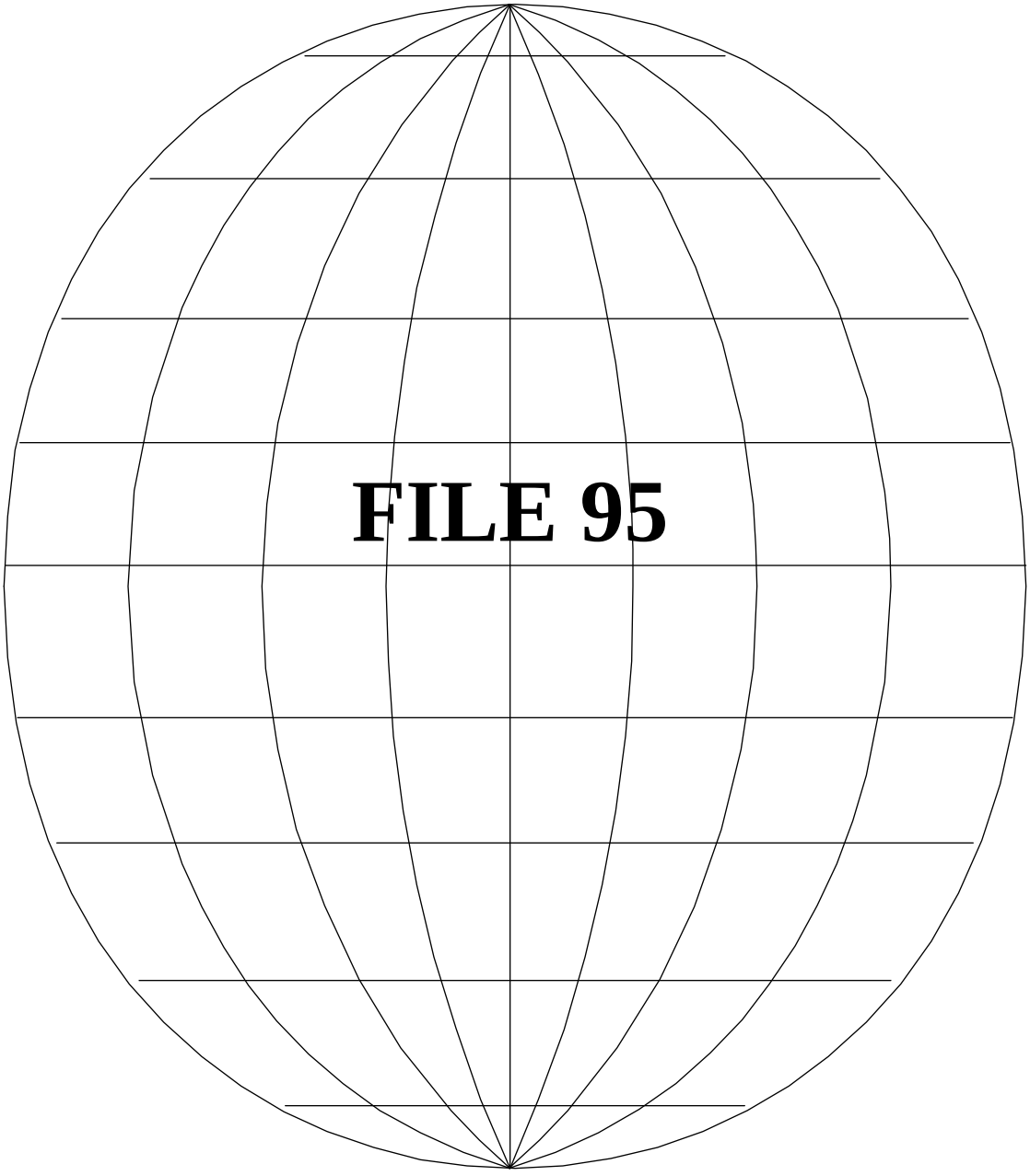

Analysis of Current Medicolegal Issues
by the Department of Legal Medicine
Armed Forces Institute of Pathology

CONTINUING MEDICAL EDUCATION
IN
QUALITY ASSURANCE/RISK MANAGEMENT

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LEGAL MEDICINE

LAPAROSCOPIC CHOLECYSTECTOMY

by PAUL J. CONNORS, M.D., J.D.
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*"The surgical word for the 1990's is **laparoscopy**. Driven by the patient's desire for less pain, an extremely short recovery period (when no complications are present), a desire for sales by the medical-industrial complex, and efforts by surgeons to keep or enlarge their market share, laparoscopic techniques, mainly cholecystectomy, are a bull market.*

Accessories to this trend are anesthesiologists, who benefit from longer operating times as the new technique is learned; hospitals, whose operating rooms are filled; and lawyers, whose personal injury suits are more numerous. Third party payers thought they would benefit from shorter hospitalizations, but because asymptomatic or mildly symptomatic patients with gallstones now become surgical patients, the number of cholecystectomies and third party costs will probably increase."[1]

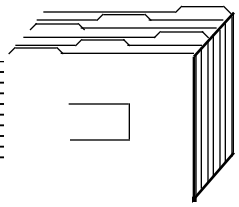
* * * * * *

The community of general surgery within the United States experienced a remarkable revolution from approximately 1989 through 1992. During that time, across the nation, the fundamental intraoperative techniques employed in the performance of cholecystectomy, the intraabdominal procedure most frequently rendered by United States general surgeons, were completely revised. In essence, conventional open laparotomy with cholecystectomy, i.e., open cholecystectomy (OC), the recognized gold standard for the treatment of gallstone disease, was replaced by laparoscopy-assisted cholecystectomy, i.e., laparoscopic cholecystectomy (LC).[2,3]

LC was initially described as a surgical encore to a gynecologic procedure in France in 1987.[4,5] The first reports from the United States derive from procedures performed in 1988.[6,7] At the time of the NIH Consensus Development Panel on Gallstones and Laparoscopic Cholecystectomy in September 1992, approximately 80 percent of cholecystectomies in the United States were being performed laparoscopically.[2]

The procedure involves distending the abdominal cavity with carbon dioxide gas and performing several sharp incisions through the anterior abdominal wall that are utilized as ports to permit the intraabdominal introduction of laparoscopic viewing and surgical instruments. These provide the surgeon with visualization and access for surgical maneuvers. The surgeon views the procedure through a video screen with magnification available. The gallbladder and its surrounding vital structures are visualized, the cystic duct and artery are isolated and divided, and the gallbladder is dissected free of its liver bed and pulled through one of the anterior abdominal wall incisions. When successfully performed, in comparison with OC, LC significantly reduces patient pain, hospital stays and postoperative convalescence.[2,8]

As is true of most revolutions, the relatively rapid adoption of LC in the United States engendered considerable controversy.[1,5,9,10] Approximately 10 percent of this nation's population, more than 20 million people, suffer gallstones, and one million new cases are diagnosed annually. In 1991, nearly 600,000 patients underwent cholecystectomy. Gallstones are the most common and most costly digestive disease requiring hospitalization in the United States, and their related annual costs exceed five billion dollars.[2,3]



At the time of the 1992 NIH Consensus Panel, approximately 15,000 surgeons had received some form of LC training. Often, this training was sponsored, in whole or in part, by instrument manufacturers. Unlike medications or medical devices, surgical procedures are not required by law to undergo pre-market testing to establish safety and efficacy. A national prospective controlled trial of LC was never undertaken. Now, it is generally conceded, none will be. Many doubt that patients could be recruited as volunteers, and some question whether such a study could be ethically undertaken.[10,11] The prospective experiences with LC of a number of groups and institutions have been published.[8,12,13,14,15] Internal experience with conventional cholecystectomy or the established literature regarding OC served as historical controls.

It has been reasonably established that, in skilled hands, clinical outcomes with LC compare favorably to those with OC. A steep "learning curve" exists, however, during the adoption of and adaptation to laparoscopic techniques when the potential for major complications and dire patient outcomes, to include death, has been realized.[8,16,17] Direct palpation is not possible. Exposure for visualization and examination can be frustrated and limited. True stereopsis is unavailable. The sentient cornerstones that have historically provided the foundation for skilled intraoperative surgical care within the abdomen are severely compromised.[18]

Professional organizations have suggested guidelines for the training of surgeons, their certification, and their clinical privileging for laparoscopic cholecystectomy.[19] New York promulgated mandatory health department regulations after reports surfaced regarding significant complications, with a number of deaths, during the introduction of LC to that state.[20] One widely noted concern is the occurrence of major bile duct injuries with LC, especially those not detected during the procedure. Further, there are perforations and other sharp injuries to vessels and bowel during LC that are either unique to the surgery or rarely encountered with OC. Again, when these occur without detection, clinical outcomes may be dire.[21]

In recent years, the surgical literature has included a number of reported series of conventional, open cholecystectomies with either no mortality or mortality at an extremely low rate and limited to older patients with serious co-morbid diseases, most often when acute cardiovascular events occurred during surgery. Mortality experienced with laparoscopic cholecystectomy is increased during the learning phase and later declines to absolute rates consistent with prior OC studies. This remains, however, rather disconcerting because LC deaths occur in a younger population with intraoperative injuries to the bile ducts or other intraabdominal organs and not secondary to significant co-morbid disease with acute cardiac arrests in older patients.[17,22,23,24,25]

THE PIAA SURVEY

The Physician Insurers Association of America (PIAA), as reviewed previously in this publication, was organized in 1977 as a national representative body of those medical liability insurance companies owned or directed by physicians.[26] PIAA maintains a Data Sharing Project regarding medical malpractice claims filed against member companies since 1985, and there are more than 100,000 malpractice claims that have been submitted to that project. The organization has also published specialized, focused reviews derived from subsets of that malpractice database.

In 1994, PIAA published a survey of malpractice claims filed with member insurers regarding all forms of laparoscopic surgery.[27] This study was undertaken in 1993, at the request of the organization's membership, and 31 of 47 PIAA constituent companies agreed to participate.

LAPAROSCOPIC CHOLECYSTECTOMY, cont'd

Those insurers are identified in an appendix to the published study. They represent, from across the United States, a spectrum of the smallest to the largest PIAA insurers.

The survey was completed by September 1993. It should be noted that, from data in the complete PIAA malpractice database, on average, 22 months pass between the time of provision of clinical services and the receipt of a malpractice claim. Further, the average time from receipt of a claim to final closure is another six years, and there are claims not closed for 10 years. This study, unlike any other focused research published by PIAA, could not be a review of closed claims and must be interpreted accordingly. PIAA deems the results preliminary. Many survey forms forwarded to participating insurance companies, due to a lack of complete legal discovery and other characteristics of malpractice claims when not closed, were returned lacking entries for all data requested.

The primary focus of the survey, given the nature of open claims, was an attempt to identify patient injuries (Table 1), along with certain demographic attributes of both providers and patients, that might be useful for loss prevention purposes.

With regard to all laparoscopic procedures, there were 615 claims reported in the PIAA survey, and they arose after the performance of 13 different kinds of surgery. The study concentrates upon the 331 claims (54 percent) that arose after the performance of laparoscopic cholecystectomy. Interestingly, the first LC related malpractice claim in the PIAA survey was filed in April 1989, rather early in the American experience with LC surgery. Among the remaining 284 laparoscopic surgery claims, the other 12 surgical procedures chiefly occurred during the provision of gynecologic services. Diagnostic gynecologic laparoscopy was the source of 50 percent of those claims (142 cases), and tubal ligation was the source of 50 percent of the remainder (71 cases).

PIAA STUDY: LC INJURY

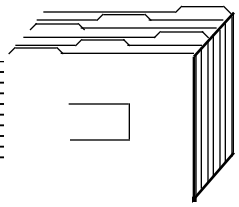
n = 347

Injury	Number
Common Bile Duct	197
Perforation, lacerations, punctures, leakage	
Hepatic Duct	45
Same injuries as above	
Bowel area	38
Same injuries as above	
Arteries & veins	32
Punctures, tears	
Fistula	8
Equipment burns	7
Retained gallstones	3
Retained surgical foreign body	2
Other	15

TABLE 1

For comparison purposes, the study organizers extracted data from 366 conventional open cholecystectomy procedures that had been the source of malpractice claims filed with the organization's general Data Sharing Project between 1985 and 1992. On average, the patients in the LC population were younger (43 years old) than those from the claims after OC surgery (46 years old). Further, the LC patients were more often female (84 percent) than in the OC cases (64 percent). Among the laparoscopic cholecystectomy claims, the provider specialty was general surgery more than 90 percent of the time (Table 2). Other specialties, however, were represented. There were three claims filed with regard to resident providers.

The most frequent adverse clinical outcome for injured LC patients was undergoing a second operation. This commonly reflected the performance of a Roux-en-Y procedure to bypass a severe bile duct injury. It is noteworthy that in 243 of the LC claims (75 percent), the injury to the patient was not recognized at the time of initial surgery. The surgeon recognized the appearance of an injury in 85 cases and, most



PIAA STUDY: LC PROVIDER SPECIALTY
n = 331

Specialty	Number	Percentage
General Surgery	304	91.8%
Cardiovascular/ Thoracic Surgery	12	3.6%
Ob/Gyn	5	1.5%
General/Family Practice	4	1.2%
Resident	3	0.9%
Colon-Rectal Surgery	1	0.3%
Gastroenterology	1	0.3%
Pediatrics	1	0.3%

TABLE 2

often, converted surgery to a conventional open cholecystectomy.

Employing an injury severity scale derived from the National Association of Insurance Commissioners, the PIAA study calculated a mean injury evaluation slightly more serious and severe for the comparison OC cases. In that group, 83 patients (22.7 percent) had died, while the mortality rate from the LC claims was 10.6 percent. The indemnity experience, however, does not conform to that data. When this study closed, in 1993, the majority of OC claims, 288 files (79 percent), were closed, and 92 cases (32 percent) had been closed with payment. The average indemnity was $96,800. In contrast, 94 LC claims (28 percent) had been closed, and 51 cases (54 percent) had been closed with payment. The average indemnity paid was $136,000.

CASE AND COMMENT: INSTITUTIONAL LIABILITY

The patient was referred to the defendant surgeon on February 15, 1990, for a consultation regarding treatment of gallstones. The surgeon had participated in and was certified as having completed a laparoscopic cholecystectomy workshop on February 10, 1990. After concluding his evaluation of the patient, the surgeon recommended that she undergo laparoscopic cholecystectomy. On the next day, February 16, 1990, the surgeon asked the president of the defendant hospital to amend his surgical privileges to include the temporary privilege of performing laparoscopic cholecystectomy with the assistance of an experienced laparoscopist.

Laparoscopic cholecystectomy was performed on February 20, 1990. The patient is described as having experienced a complication of that procedure that resulted in significant hemorrhage and death. In time, a malpractice suit was filed against the hospital, the surgeon, and the assisting physician. Prior to trial, the defendant hospital argued that it should be granted summary judgement and dismissed from the litigation, contending that longstanding state law was inconsistent with imposing liability upon a hospital for the care of a private patient by an independent staff surgeon. Motion for summary judgement was denied by the trial court, denial of that motion was affirmed at the Georgia Court of Appeals, and certification to the state supreme court for further appeal was declined.[28]

For purposes of the appellate opinion, it was considered true as alleged by the plaintiff, the patient's estate, that the assistant-proctor surgeon in this case was a specialist in gynecology who admitted that he was without any skill or experience in the performance of laparoscopic cholecystectomy. There was no evidence that he had ever performed the surgery.

Utilizing more recent and relevant precedent from the Supreme Court of Georgia and from authoritative cases in other jurisdictions, the appellate court determined that it was an obligation of all hospitals in the state to assume a direct and independent legal responsibility for every hospitalized patient and to take all reasonable steps necessary to insure that staff physicians were

LAPAROSCOPIC CHOLECYSTECTOMY, cont'd

qualified for any clinical privileges granted. The court returned this case for trial with an expectation that, were facts proven as alleged, the hospital could be held liable for this patient's death due to negligent administration either in the granting of privileges to or the supervision of an independent medical staff member when performing laparoscopic cholecystectomy.

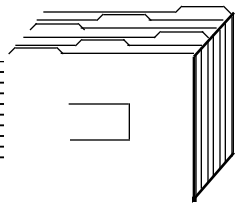
* * * * * *

Few judicial opinions from cases involving laparoscopic cholecystectomy have been reported in the on-line databases available to our office. As suggested by the PIAA study, this likely represents the somewhat characteristic "long tail" of malpractice disputes generally and may reflect specifically a prolongation of that time after the introduction of a novel form of treatment. When LC related malpractice cases eventually arrive in court, they will be subjected to lengthy deliberative opinions. No one today can presage those analyses, but the general categories of probable allegations are clear.[29]

One allegation will be that the surgeon in question, due to limitations of training or skill or experience, should never have performed the procedure. This type of allegation, a double-edged claim, poses simultaneously the potential for imposing individual liability on the surgeon and institutional liability on the health care organization that permitted an incompetent staff member to perform the procedure. Every detail of the surgeon's laboratory experiences with this procedure, the specifics of the initial and ongoing supervision while performing the surgery, the nature of the certification of competence, and the history of assisting others and being assisted in performing the procedure will be investigated, documented, and introduced into evidence. By necessity, the hospital's practices and procedures will be similarly scrutinized.

Another form of allegation will be that the surgery undertaken was, in fact, negligently performed. Evidence to support a contention of technical deficiency in the surgery as performed will be sought from the nature of the injury suffered, the findings at the time of later treatments, whether rendered by the initial provider or others, and the results of autopsy, where applicable. A striking medicolegal novelty could arise during LC related litigation, because many of the intraoperative maneuvers undertaken during laparoscopic cholecystectomy are videotaped. Those videotapes will be subpoenaed and critically analyzed. Usually, courts permit a weighty inference against the interests of any party who, charged with the responsibility of maintaining physical evidence such as a videotape, allows that evidence to be misplaced or lost or altered.

Lastly, allegations premised upon a lack of informed consent can be expected in LC malpractice cases. Disclosing to patients an adequate amount of information regarding the risks and benefits of a proposed therapy that is novel or under investigation presents serious challenges to all practitioners. Courts have generally voiced a desire that patients undergoing any medical procedure be adequately informed of the "material" risks, benefits, and alternatives.[30] The literature regarding laparoscopic cholecystectomy seems to establish, minimally, that the risks associated with the procedure's learning curve are undeniably material. Furthermore, the literature, on its face, already has proclaimed another form of surgical treatment a "gold standard" alternative, readily available and well-established across the nation.[23] Should "patient demand" be proffered as having forced the hand of surgical professionals into performing LC, more than two decades of developments in American civil law regarding consent to medical treatments clearly predict a resolute judicial response: *That better be* ***informed*** *patient demand!*



CONCLUSION

In 1989, McSherry reported the last installment of a 52-year consecutive registry of patients, from 1932 through 1984, who underwent surgery for nonmalignant biliary tract disease at a single medical institution, the New York Hospital-Cornell Medical Center.[23] The complete registry referenced 14,232 patients, and the 1989 report emphasized the previously unreported six-year experience from 1978 through 1984. The latter years of surgery, all conventional open cholecystectomies or related procedures, were contrasted with prior published reports.[31,32,33] The article, referring to this surgery as the "gold standard" for the treatment of nonmalignant biliary tract disease, compares and contrasts the experience of patients from the registry at different times, especially with regard to the rate and the nature of complications and the rate and the causes of death.

When published, the author's clearly enunciated purpose was to contrast this experience with certain nonsurgical alternatives determinedly advocated at that time, namely, bile acid therapy, alone or in conjunction with extracorporeal shock-wave lithotripsy, and contact dissolution. In the opinion of McSherry, among the 30 deaths that occurred in the 2,386 patients surgically treated from 1978 through 1984, there was only one patient who was a potential candidate for bile acid therapy or lithotripsy, given the applicable criteria limiting their utilization. He remarked,"This study clearly illustrates the fallacy of attempting to compare two entirely different treatment modalities in two different patient groups in the absence of a prospective, randomized study. There is no validity to any statistical comparison of the risk of cholecystectomy with that of bile acid therapy alone or in combination with lithotripsy."[23]

McSherry commented that all of the available nonsurgical techniques suffered from the serious consequence of leaving a diseased gallbladder in-situ and permitting the recurrence of gallstones. He concluded with the following statement: "The only real justification for the nonoperative solutions to gallstone disease is the infrequent but often devastating complication of intraoperative common bile duct injury. This complication still occurs despite advances in surgical training. The burden that it frequently imposes is a shortened life span frequented by repeat operations interspersed with bouts of cholangitis. If this disaster could be eliminated there would be no justification to seek alternatives to cholecystectomy."[23] Simple logic would appear to argue that this author, along with other leading American general surgeons in 1989, would have applied equivalent analytical criteria to any proffered **surgical** alternative to the established procedure. Simple logic, however, does not always control events.

No evidence yet exists that a deluge of liability claims and payments has followed the relatively rapid adoption of LC across the United States. The performance of standard open cholecystectomy historically has occasioned the most numerous malpractice claims filed against general surgeons after intraabdominal surgery.[34] A significant amount of time will need to pass before sufficient data is available to substantiate a conclusion that LC malpractice claims have not only replaced OC cases but disproportionately so, in frequency or severity or both. The metaphor of an inundation is not yet justified.

There are, however, distant rumblings, and there may well be reason to keep one's medicolegal foul weather gear at hand. The Association of Trial Lawyers of America has impaneled a "Laparoscopic Litigation Group" to serve as a national resource center and informational clearinghouse for plaintiff lawyers filing claims regarding this type of surgery. [Personal communication. Association of Trial Lawyers of America, Laparoscopic Litigation Group, T. Tsarouhas, Esq.] In 1992, Scott, *et al.*, reported a survey reviewing the 23 series previously published in

the surgical literature regarding outcomes for 12,397 patients undergoing LC.[16] The authors then estimated that more than 150,000 LC surgeries had been performed in the United States. Reports of experiences from academic centers or from academic centers in association with community providers may not accurately reflect the operative experiences of surgeons elsewhere. Others have suggested that medical referral centers have become increasingly more involved in the secondary treatment of patients who have experienced serious LC complications.[2]

Lawyers charged with the responsibility of defending physicians in malpractice cases involving invasive treatments take great comfort when that medical care is provided after having been proven scientifically "standard" in sound clinical trials. Similar to the reaction of physicians, those attorneys are granted considerable security when such evidence exists and supports either their client's providing a treatment or declining to do so.[35,36,37] Legal arguments that the doctor's action was reasonable and prudent and knowledgeable can be persuasively evinced when the decision is so wisely substantiated. Highly invasive surgery that causes serious patient injuries can pose particular difficulties for the provider's legal representatives when a malpractice claim arises in the absence of sound clinical evidence supporting the procedure's safety and efficacy.

For centuries, our common law has construed the doctor-patient relationship as, at once, professional and fiducial. The interests of the patient, thereby, are legally paramount and granted both deference and protection by the courts. As the quotation that introduced this article suggests, there appear to have been a number of parties served and varied interests advanced during the revolutionary adoption of laparoscopic cholecystectomy in this country. As difficult as are predictions of legal events, the resilience of precedent in these regards makes clear the unfavorable judicial reaction should it be proven that the care, the health, or the safety of a patient was jeopardized when the treating physician or those legally associated with that physician served primarily, in fact, some other master.

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LEGAL MEDICINE

LAPAROSCOPIC CHOLECYSTECTOMY: A STUDY FROM THE DOD CIVILIAN EXTERNAL PEER REVIEW PROGRAM

by GEORGIA A. MARTIN, R.N., J.D., Ph.D.

In recent years, laparoscopic cholecystectomies have virtually replaced open surgical cholecystectomies.[1] As the previous article noted, however, controversy has arisen particularly because of the rate of common bile duct injuries during a surgeon's early cases when performing laparoscopic cholecystectomies.[2]

At the request of the Department of Defense (DoD), the Civilian External Peer Review Program (CEPRP), under the direction of the Uniformed Services University of the Health Sciences (USUHS), completed a study on laparoscopic cholecystectomy within the military health service system.[3] It is the first study that included every surgeon within a large medical system who performed a laparoscopic cholecystectomy during a specific period. Particularly noteworthy is that the investigators obtained complete medical records on 99.38 percent of the 5,642 patients who underwent this surgery in military hospitals from July 1990 through May 1992. The study addresses the clinical processes, outcomes, and resource implications associated with laparoscopic cholecystectomy. Recently, a detailed report of the methods, results and conclusions was published in the peer reviewed surgical literature.[4]

The CEPRP study included 8,560 cholecystectomies performed at 89 military hospitals from July 1990 through May 1992. Of these, 2,918 were open procedures and 5,607 were laparoscopic procedures (only 35 of these cases had missing or incomplete records). Of the laparoscopic procedures, 5,154 were completed laparoscopically and 453 (8.1 percent) were converted to open procedures.

Data from laparoscopic cholecystectomies that were examined include patient population demographics, mortality and morbidity rate, rate of conversion to open cholecystectomy, length of stay, resource use, and cost of care. Analyses were performed for all DoD and also by branch of service and geographic region. The average age of the patients in the CEPRP study was 42.1 years. The age range was 6 to 94 years. Women accounted for 77.3 percent and active duty members 15.3 percent of the patient population.

COMPLICATION SEVERITY BY SERVICE BRANCH

BRANCH	CASES	COMPLICATIONS		
		Severe (%)	Non-Severe (%)	Total (%)
Army	2,309	60 (2.6%)	87 (3.8%)	147 (6.4%)
Air Force	1,696	51 (3.0%)	59 (3.5%)	110 (6.5%)
Navy	1,602	43 (2.7%)	83 (5.3%)	126 (8.0%)
Total	**5,607**	**154 (2.7%)**	**229 (4.1%)**	**383 (6.8%)**

TABLE 1

LAPAROSCOPIC CHOLECYSTECTOMY: CEPRP, cont'd

Surgical Complications

The frequency of complications from laparoscopic cholecystectomies throughout DoD was 6.9 percent. The Army, Air Force and Navy complication rates were 6.4 percent, 6.5 percent, and 8.0 percent, respectively. The Army and Air Force rates were very similar to those reported in other studies.[5,6,7] A breakdown of the complications as either severe (e.g., bile duct injury) or non-severe (e.g., prolonged ileus, wound infection) is shown by branch of service in Table 1. The Army, Air Force and Navy rates of severe complications were 2.6 percent, 3.0 percent and 2.7 percent, respectively.

Conversion to Open Procedure

The reasons for converting laparoscopic cholecystectomies to open procedures were divided into four categories: preoperative conditions (e.g., adhesions, aberrant anatomy), intraoperative events (e.g., bleeding), suspected bile duct injury, and specific technical difficulties (e.g., inadequate visualization, difficult trocar placement). Laparoscopic procedures were converted to open procedures in 8.1 percent of DoD cases. The Army, Air Force, and Navy conversion rates were 8.9 percent, 5.2 percent, and 9.9 percent, respectively. These findings are consistent with the two percent to ten percent range for conversion rates reported in the literature.[8,9]

A surgeon's decision to convert to an open procedure can involve factors not discernible when the procedure was commenced (e.g., aberrant anatomy). Moreover, the importance of converting to open cholecystectomy when problems arise that cannot be readily addressed with laparoscopic techniques is repeatedly emphasized to military surgeons. A conversion rate near the upper end of the range reported elsewhere, therefore, does not necessarily reflect inadequate surgical skill.

Resource Use

The average hospital stay for patients undergoing laparoscopic cholecystectomy was 3.7 days, compared to 8.2 days for converted procedures. The average for all cases was slightly over four days. Not surprisingly, the study found direct relationships for the complication rate with average length of stay and for the conversion rate with average stay.

Length of stay and the cost for cases either completed laparoscopically or converted are displayed in Table 2. When the DoD cost for a "general surgery day" ($1,070) is applied, the average cost for cases completed laparoscopically was $3,959, and the average cost for cases converted to open procedure was $8,774. The converted cases cost DoD $4,815 more per case and almost $2.2 million over the two year study period.

RESOURCE USE: COMPLETED vs. CONVERTED

LAPAROSCOPIC PROCEDURE	CASES	HOSPITAL STAY (days)	AVERAGE COST PER CASE ($)
Completed	5,154	3.7	3,959
Converted	453	8.2	8,774

TABLE 2

FOLLOW ON STUDY

The findings of this study indicate that the frequency and severity of complications, length of hospital stay, and the rate of conversion from laparoscopic to open procedures parallel data reported in the literature. CEPRP is currently conducting a follow on study with USUHS on laparoscopic cholecystectomy within military medicine for the period between January 1993 and May 1994 with the goal of developing practice guidelines. In addition, the feasibility of establishing a laparoscopic cholecystectomy registry at USUHS to track bile duct injuries within the MHSS is being evaluated.

Further information regarding CEPRP efforts to study laparoscopic cholecystectomy are available from David C. Wherry, M.D., or Lt Col Michael Morohn, USAF, MC, Uniformed Services University of the Health Sciences, School of Medicine, 4301 Jones Bridge Road, Bethesda, MD 20814; or from Raymond S. Crawford, M.D., Forensic Medical Advisory Services, Inc., 11300 Rockville Pike, Rockville, MD 20852.

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CONSULTANT'S CORNER

MEDICAL RECORDS

by Dorothy Rasinski, M.D., J.D.

In this article, the Former Associate Chief of Staff for Education at the Long Beach VA Medical Center discusses medical records from a legal perspective. A President Emeritus of the American College of Legal Medicine, the author publishes, lectures, and consults extensively on malpractice prevention, risk management and bioethical topics.

INTRODUCTION

In today's complex health care environment, medical records take on increasing importance in documenting patient care. A good medical record constitutes a reliable means of communication among various professionals delivering health care to a patient. With the large number of providers who practice in any medical center or outpatient clinic, it is impossible for one practitioner to inform all the others individually when reporting findings, conclusions, recommendations, or follow-up observations. In such a setting, the sole means of effective communication is the medical record. Accordingly, a carefully prepared and comprehensive medical record is the patient's best assurance of quality care and continuity of that care.

Secondly, with the advent of health care reform, increasing importance has been granted clinical guidelines in arriving at diagnoses and determining propriety of treatment. Careful and thoughtful medical record documentation provides strong evidence of practice within guidelines and, when deviation from guidelines becomes necessary, support for a deviation. In many settings, either compliance with guidelines or careful documentation supporting a deviation may be necessary to assure reimbursement, the appropriate privileging of providers, or certification of the facility.

Thirdly, administrative programs, such as Total Quality Management (TQM) and Continuous Quality Improvement (CQI), have heightened the emphasis placed on the review of medical records to monitor and assess clinical outcomes.

Given our society's present medicolegal climate, however, the greatest concern regarding the medical record for many physicians is its use as evidence when a claim of medical professional negligence or malpractice arises. In any malpractice trial, the most important evidence presented to the court is the medical record. A good record bespeaks good medical care. If the clinical outcome is especially adverse and the pertinent medical records are particularly deficient, liability may be inferred. A significant percentage of medical malpractice suits are rendered indefensible due to material deficiencies in the related medical records. This is true even when appropriate care may have been actually rendered. Rarely, if ever, can a malpractice claim be defended successfully without a sound medical record.

Since most malpractice suits are not tried for several years, and the memories of individuals can be unreliable in such circumstances, the medical record assumes added importance.

In a malpractice suit, the physician's treatment of the patient is measured against what the law calls the "standard of care." The court assesses the physician's professional conduct to determine whether it adhered to or deviated from the standards of practice required by both medicine and the law. The medical record, therefore, provides a legal index or guide to the professional conduct under scrutiny. It supports conclusions regarding the physician's competence and, as a matter of law, his credibility.

Any legal opinion is a retrospective judgement. Accordingly, judges instruct attorneys what to look for in medical records, particularly as they can be construed as a barometer for the standard of care delivered. The term "standard of care" is both difficult to define and subtle. There are no simple responses to the question, "What is the standard of care?" Rather, it is best defined as the requirement that a physician use his best judgement, the way a prudent and equally well-trained physician would in the same or similar clinical circumstance.

To determine whether or not a physician used his "best judgement", it is important to examine two conditions precedent to that ideal: first, that the physician possess knowledge; and, second, that he exercise or apply that knowledge in a careful and skillful manner. If the physician hopes to proffer a medical record to defend his professional conduct, he needs to ensure that those conditions are clearly fulfilled within that record.

MEDICAL RECORD CONTENTS

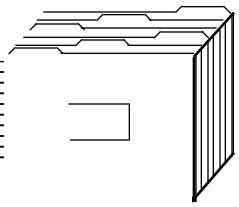
General Guidelines

Entries in the record should demonstrate the physician's education, training and experience as applied to a particular case or clinical situation. In the eyes of the law, the record should reflect the physician's skill, i.e., clinical competence, and the effective and judicious way in which he has applied his knowledge. This surpasses merely gathering and recording salient medical facts, although that is important. It means revealing one's professional thinking and judgement. This minimizes the risk that a diagnosis or treatment decision will be subjected to a "second guess" or misinterpretation.

The manner in which information is conveyed makes a substantial difference. Frivolous comments, use of the vernacular, frequent sprinkling of meaningless abbreviations, or statements of moral judgement about patients, their families, or significant others are inappropriate. They suggest that the physician acted in a manner that was too informal, nonmedical, or unprofessional.

Specific Elements

A medical record should: (1) establish the most likely cause of the patient's problem, (2) support the diagnosis, (3) outline the treatment and management of the patient's condition, and (4) describe the patient's response to treatment or, if no response, the provider's subsequent action. Either too little or too much information causes problems. The record must provide enough meaningful medical data that another practitioner could step in and take over, when the attending physician is unavailable or should the patient be transferred.



An adequate medical record tells the clinical story of the patient's problem, describing its complexity and demonstrating its receipt of proper professional attention. Such a record is carefully prepared, complete, accurate, legible, germane, relevant, timely. It is wise to include a problem list, with new problems added as they develop and old ones addressed as corrected, stabilized, controlled, or eliminated. Any special circumstances under which the patient is evaluated, such as an emergent or urgent situation, or one in which the patient is hostile, uncooperative, irrational, psychotic, intoxicated, or incompetent should also be recorded.

Prescribing practices are not usually questioned unless the record reveals an inadequate clinical evaluation, i.e., history, physical examination and appropriate ancillary studies, before a prescription is written. At a bare minimum, particularly in the case of controlled substances, the record should include entries that are consistent with a valid therapeutic indication for the prescription.

Informed Consent and Advance Directives

Before performing a complicated diagnostic or therapeutic procedure, particularly one that is invasive or requires anesthetic premedication, or before treating a patient with drugs that risk significant complications or side effects, the physician should obtain and adequately document the patient's informed consent. The record should reveal that the patient has been informed of the diagnosis, the contemplated procedure, its indications, associated risks, complications or side effects, the goal to be achieved, the reasonably available alternatives, and the expected outcome if nothing is done.

A laundry list need not be written out, but merely the fact that the most significant items among those categories were discussed with the patient, that the patient understood and agreed to the treatment after having been provided the opportunity to ask questions. A brief contemporaneous note to that effect, either in the outpatient or hospital record, should suffice to demonstrate informed consent. Hospital protocols may also require the patient's signature on a consent form, which should be witnessed, dated, and filed.

With an increasing focus upon the appropriate use of sophisticated medical technology at the end of life, a new concern with medical records has arisen. The law has stated that patients have a recognized right to be more directly involved in deciding the course of their care. Their wishes, however, can conflict with those of their family members or the recommendations of their physicians. All such discussions with patients or their surrogates, and all orders to institute, withhold or withdraw treatment must be clearly documented in the medical record. The record should also include relevant forms or directives executed by the patient. These should be consistently flagged so that, when urgent or emergent situations occur, the available treating staff can quickly and accurately ascertain the patient's expressed wishes and institute or withhold therapy accordingly.

The Competent Medical Record

The medical record should demonstrate rational decision making throughout. Documenting the selection of germane clinical facts and the synthesis of such facts into a differential diagnosis is a fundamental means to that end. The record should always provide sufficient data to explain how the professional's thinking led to a diagnostic or therapeutic decision. Moreover, the physician's professional conduct should be consistent with the analysis reflected in the medical record. If not, the record should carefully

reconcile, by appropriate comment, any disparity between thought and action. A failure to provide that reconciliation may later support an inference of incompetence on the part of the physician.

SPECIAL PROBLEMS

Alterations

Legally, the provider who appears recurrently to find himself in deep water is the one who alters a medical record "after the fact." It is bad enough to prepare records that do not adequately document medical care as rendered, but to alter the record, especially after a claim is filed or following a bad result, is potentially disastrous. Judges and jury members are naturally inclined toward a common sense postulate under such circumstances: if the physician had nothing to hide, why meddle with the record?

Should an erroneous order need rewriting or should an entry have been placed in the wrong patient's record, one should take care not to let a necessary correction appear to be an attempt to conceal. A single line should be drawn through the erroneous entry so that it may still be read, and that entry should be initialed, with the date and time noted. At the next available appropriate place in the record, another note should be written to explain the correction. The physician's signature, with the date and time, should be appended to the new entry, corresponding with the first line-out.

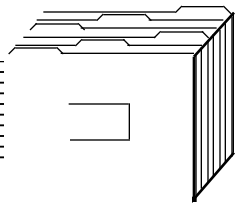
Internal Inconsistencies

One of the more unusual circumstances in which providers are "hung out to dry" on their records is when those records manifest a lack of internal consistency. A pertinent example involved a busy physician who noted in an admission history that the patient, a longstanding diabetic with severe peripheral vascular disease, had previously undergone a right below-the-knee amputation. Further, the patient was also described as experiencing incipient vascular problems and a plantar ulcer on the left foot. Unfortunately, the admission physical examination included a notation that the physician had palpated bilateral pedal pulses. At a subsequent malpractice trial, regarding an issue totally unrelated to the vascular problem and its treatment, this discrepancy created great embarrassment and unnecessary confusion.

Internal inconsistencies can also arise when notes are not written in a timely manner. Operative reports should be dictated as soon as possible after the procedure, especially when the surgery is unusually complex or complications have occurred. It is difficult, if not impossible, to defend a malpractice suit alleging negligent performance of complicated surgery when the operative note is dictated six months after the procedure was performed, reads like a textbook description, and mentions no problems. In one such case, the contemporaneously handwritten postoperative note described in detail the difficulties encountered by the surgeon during the procedure. Progress notes in the medical record from weeks after the procedure also gave contradictory information and described further the results of intraoperative errors and difficulties. Given these circumstances, the only sensible recommendation was to settle the case as soon as possible.

Jousting

Feuds or quarrels between physicians, or between physicians and other providers, have no place in the medical record. They may help demonstrate to a court that the staff was so involved in waging internecine battles that little or no attention was paid to the patient.



For example, one internist always referred his patients who required surgery to a particular surgeon noted for his technical skill but not his knowledge of postoperative intravenous fluid management. The surgeon operated on a patient referred to him by the internist and proceeded to write intravenous fluid orders. The internist conducted rounds later that day and, dissatisfied with the surgeon's orders, wrote a progress note: "This horse's __ may know a lot about surgery, but he knows absolutely nothing about fluids. Fluid orders changed - see order sheet." The surgeon made rounds early the next morning and drafted his own progress note: "If I am such a horse's __, why do you keep calling me back to do your surgery?" Unfortunately, the patient died of complications. There was no evidence of any negligence or malpractice involved in the case. The defense of a suit brought by the surviving family was significantly compromised, however, by the unnecessary, inappropriate, and unwarranted comments of the two physicians involved.

When there is professional disagreement about the nature of orders to be written or similar issues, the topic should be discussed directly between providers. Comments in the record should always reflect a professional dialogue, not personal diatribes.

Maintenance

With medical care today more frequently being provided in an outpatient setting, it is critically important that the record of all visits by a patient to a physician be carefully maintained, lest it be suggested later that the physician failed to employ adequate diligence or that he abandoned the patient. In particular, the record should carefully document changes in the medical care. These include: (1) changes in diagnosis or impression; (2) changes in treatment; (3) new diagnostic procedures to be undertaken, with results of those studies; and (4) changes they suggest in diagnosis or treatment.

CONCLUSION

Experts in the field of medical records recommend that, at a minimum, six categories of information be provided in a medical record: (1) a complete history with a description of the present ailment or injury, recorded as nearly as possible in the patient's words; (2) the report of a physical examination revealing objective findings regarding subjective complaints and including significant negatives; (3) a record of diagnostic tests and all similar reports received concerning the patient; (4) an impression or a diagnosis (when a physician is able to form only an impression in the absence of additional diagnostic procedures, the word "diagnosis" should be avoided); (5) a record of treatment, with medications prescribed and procedures recommended or performed; and (6) the patient's response to treatment along with any indicated alterations in the treatment plan.

When a malpractice claim arises, the medical record may be one's only source of information regarding the diagnosis, the treatment plan, and the final evaluation and results in a particular case. Keeping carefully prepared, complete, accurate, legible, and timely medical records is not some incidental, ancillary legal obligation externally imposed on health care providers. It is, rather, an inherent component of sound medical practice and one that can afford the provider who renders proper care a nearly impregnable defense against a claim of negligence.

LEGAL MEDICINE

PEDIATRIC BACTERIAL MENINGITIS

by ALAN R. FIGELMAN, COL, MC, USAR*
and STEPHEN V. MAWN, CDR, MC, USN

BACKGROUND

The medical, social and financial consequences of pediatric bacterial meningitis can be catastrophic for patients and their families. Accordingly, medical malpractice claims that involve treatable meningitis can be unusually expensive in money and in time. A study of resolved emergency medicine claims from the last decade found that, although delayed diagnosis of meningitis was a relatively infrequent source of paid claims, it resulted in nearly ten percent of the total dollar amount paid for all claims.[1] A neurologically debilitated infant can live many years, given modern medical and nursing care. Moreover, the costs incurred simply for resolving meningitis cases are substantial, because they often involve complex medicolegal issues.

We reviewed the Department of Defense database of closed malpractice claims (n=2814) and found 26 cases involving pediatric bacterial meningitis. There were 12 paid claims. The mean amount paid, skewed by several relatively large payouts, was $661,000, and the median was $162,500. There was one patient who was eight years old, while the others were three years old or younger. In 13 cases, the bacterial species was specified: five cases involved Group B streptococcus; four cases each involved *Hemophilus influenzae* and *Streptococcus pneumoniae*. Conspicuous by their absence were cases that followed either *Escherichia coli* or *Neisseria meningitidis* infections.

In bacterial meningitis, circulating bacteria enter the central nervous system through vulnerable points along the blood-brain barrier. The functional status of the patient's immune system is a key variable in determining the clinical presentation, severity and sequelae of bacterial meningitis. The responsible bacterial species is another. Since both the immunological integrity and the types of bacteria causing meningitis vary with age, meningitis has different clinical presentations and consequences throughout childhood.

The following cases from the Armed Forces Institute of Pathology, Department of Legal Medicine, are reviewed to illustrate some of the difficult medicolegal issues that face physicians when diagnosing and treating children with bacterial meningitis or associated occult bacteremia.

CASE 1

A 15-day-old infant with fever, decreased appetite and irritability was taken by ambulance to the emergency department of a military hospital. The patient, who was the product of an uncomplicated pregnancy and delivery at term, had gained 21 ounces since birth. Examination by a family practitioner revealed a sleepy but arousable infant with a left otitis media and a fever of 104°F. The infant's temperature decreased to 102°F after acetaminophen was administered. An ounce of a glucose and electrolyte solution was taken by mouth without difficulty. Although hospital admission was discussed with the mother, the physician decided to discharge the infant home and treat him with amoxicillin (50mg/kg) and acetaminophen.

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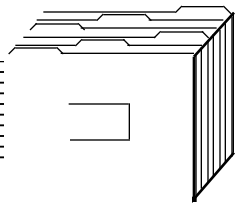


PEDIATRIC BACTERIAL MENINGITIS, cont'd

Four hours later, the patient's father called the emergency room and reported that the infant was experiencing respiratory difficulty. Due to inclement weather, the parents were directed to a civilian community hospital located near their residence. A pediatrician was notified and arrived at that hospital two hours later. Over the next hour, the patient was administered dexamethasone, phenobarbital (for suspected seizure activity), amoxicillin, and gentamicin. During preparation for a lumbar puncture, the baby suffered cardiac arrest. Once intubated, he was transferred to the intensive care unit of a nearby medical center.

A diagnosis of Group B streptococcal meningitis and sepsis was confirmed. Despite aggressive treatment, the patient developed diffuse intravascular coagulopathy and died the following day.

Several months later, a claim alleging negligence by military health care providers was submitted. Reviewers opined that "the standard of due care was violated" while recognizing that "[t]he outcome might well have been the same . . . even if the medical care rendered had been irreproachable." An offer to settle the claim was accepted by the parents.

COMMENTS

The physician at the military hospital failed to respond appropriately to fever in a patient less than two months old. According to some experts, **any** temperature above 100.4°F in this age group must be considered symptomatic of occult bacteremia. When meningitis develops in patients under two months, the reported mortality rate is between three and seven percent, with a peak at 30 percent for newborns. Long term neurologic sequelae develop in approximately a third of survivors.[2]

Due to their immature immune systems, infants less than one month old are quite susceptible to organisms acquired either at birth via contact with the mother's genital tract or bowel flora or from postpartum contact with the hands of nursery personnel and others. In these infants, Group B streptococcus and *Escherichia coli* are responsible for a large majority of infections. Other gram negative bacilli and *Listeria monocytogenes* comprise most of the other bacterial pathogens in this age group.[3]

In infants one to three months of age, immunocompetence dramatically improves. By three months of age, the encapsulated bacterial organisms, *Hemophilus influenzae, Streptoccocus pneumoniae,* and *Neisseria meningitidis*, become the organisms primarily responsible for bacterial meningitis. In the interim two month period, those three and the organisms that cause infections in neonates are usually implicated in occult bacteremia.[4]

Clinical strategies to identify so-called "serious bacterial infections" in infants who are less than two months lack sufficient sensitivity to be reliable. If the infant is less than a month old and febrile, a complete evaluation for sepsis is required, hospitalization recommended, and 48 hours of intravenous antibiotic therapy usually mandated. Diagnostic testing should include a complete blood count, a chest radiograph, urinalysis, and cultures of urine, blood and CSF. If the infant has diarrhea, a stool culture with examination for polymorphonuclear leukocytes should be performed.[5]

For febrile infants in the second month of life, the same diagnostic tests are necessary. Some clinical studies have concluded that, if the initial workup is negative, outpatient follow-up with careful observation in combination with 48 hours of intramuscular antibiotic therapy (ceftriaxone) is acceptable. Although few clinicians would argue with hospitalization in this age group, the

following criteria have been proposed to identify infants less likely to suffer serious bacterial infections: (1) the infant appears well; (2) the infant has been previously healthy (full term, no prior antibiotics, no treatment for unexplained hyperbilirubinemia, no hospitalization at birth for longer than the mother); (3) no source of infection is identified; and (4) lab studies are normal with a white blood cell count between 5,000 and 15,000, an absolute band count less than 1500/mm, a spun urine sediment with less than 10 WBC/hpf, and a stool specimen in diarrhea with less than 5 WBC/hpf. When all these criteria are met, the risk of serious bacterial infection in a febrile two month old is significantly reduced. Careful outpatient observation, after thorough evaluation and intramuscular antibiotic treatment, has therefore been proposed as an acceptable alternate treatment plan.[6]

CASE 2

A 10-week-old girl was brought to a civilian community hospital for excessive crying and possible constipation. A ten-day course of amoxicillin for otitis media had concluded four days previously. The child was discharged home with a diagnosis of possible colic, following a physical examination notable only for irritability. Simethicone drops and a decongestant were prescribed.

Three days later, the parents telephoned the pediatric clinic of a military treatment facility and reported the child's persistent irritability. One hard stool had passed per day, and the infant was otherwise described as sleepy. No clinic appointments were available. The next day, the parents demanded an appointment, and the child was examined by a pediatrician assigned to walk-ins. "Screams like in pain, constantly" was documented as the chief complaint, paraphrasing the mother's description of the patient's condition during the previous 48 hours. The infant had lost one pound since the first visit, the temperature was 101.6°F, and the physical exam was recorded as otherwise normal. The child was discharged home with a diagnosis of constipation. Karo syrup was added to the treatment regimen.

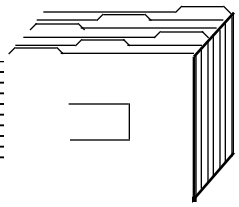
The patient was unresponsive upon presentation to the emergency department of the military medical facility two days later. Findings included asymmetric pupils, a temperature of 103.2°F, and a respiratory rate of 75. She suffered a generalized seizure and was intubated. Chloramphenicol, amoxicillin, Dilantin®, and Valium® were administered. Within two hours, the child was transported to a civilian hospital, where she died shortly after admission. Cerebrospinal fluid cultures grew out *Hemophilus influenzae* type b.

In time, the parents filed a medical malpractice claim. Reviewers noted that the case would be "difficult to defend" and that the claimants "could easily find respected experts to support their position that a standard of care was breached."

COMMENTS

In this case, providers failed to appreciate the importance of multiple parental reports regarding an inconsolable infant. The appearance of the irritable and inconsolable febrile infant should warn health care providers of impending occult bacteremia and serious bacterial infection. Children between the ages of 3 and 36 months who appear toxic require hospitalization and evaluation for sepsis.

A toxic appearance includes lethargy and evidence of poor perfusion with marked hypoventilation, hyperventilation, or cyanosis. "Lethargy" may manifest itself as poor eye contact, failure to recognize parents, or non-interaction with persons or objects. The classic



clinical signs of nuchal rigidity, stiffness, headache, and vomiting may accompany toxic appearance in a serious bacterial infection and meningitis, but the presence of irritable lethargy is more sensitive than any other indicator in infants.[8]

Clinical findings in children between 3 and 36 months may prove problematic. If the temperature is less than 39°C (102°F) in a relatively normal appearing child, no tests or treatment are necessary. With a temperature of 39°C or greater and no identifiable source, a white blood cell count should be obtained. A WBC over 15,000 compels the presumption of occult bacteremia.[5] Regarding children with occult bacteremia who are discharged home without treatment, 56 percent suffer persistent fever, 21 percent experience persistent bacteremia, and 9 percent develop meningitis. These risks are substantially reduced by administering antibiotics.[8]

Blood cultures are positive in less than 10 percent of children with possible occult bacteremia. *Streptococcus pneumoniae* accounts for 85 percent of positive blood cultures, *Hemophilus influenzae* and *Neisseria meningitidis* for 10 and 3 percent respectively.[5] Meningitis is four times more likely in infants with H. flu positive blood cultures than with Strep pneumoniae positive cultures. Ceftriaxone (50 mg/kg) has been effective in thwarting meningitis while awaiting blood culture results.[8]

The medical care rendered in the aforementioned case occurred prior to routine vaccination with Hib at two months of age. With the advent of an effective vaccine to combat H. flu, other pathogens (e.g., resistant Strep pneumoniae) may emerge, and recommended antibiotic therapy may need to be altered.[9] The most significant therapeutic advantage of parenteral antibiotic therapy in comparison with oral antibiotics has been realized with infections caused by H. flu.[5] The antecedent full course of amoxicillin in Case 2 may have masked symptoms and physical findings on presentation, obscured diagnostic tests, and contributed to the delay in diagnosis.

CASE 3

During a two-week period, an eight month old girl was evaluated for similar complaints on five occasions in the emergency department of a military hospital. At the first visit, the infant was experiencing nasal congestion with a history of fever. After a negative physical examination, acetaminophen was prescribed for an upper respiratory infection (URI). One week later, a pediatrician on duty examined the child with a history of fever to 105°F and nasal congestion. Her temperature was 101.6°F in the emergency department. URI remained the diagnosis, and a decongestant was added to the acetaminophen for symptomatic treatment.

Five days later, a physician in the emergency department reevaluated the infant. The history included listlessness, poor sleeping, and fever. The recorded physical examination noted a lethargic child with nasal congestion and a fever of 102.7°F. The physician, an obstetrician, concurred with the prior diagnosis of URI and recommended follow-up in the pediatric clinic the next day.

The child returned to the emergency department 18 hours later. An internist obtained a history of fatigue, difficulty sleeping, and hoarse cough. The temperature was 103.3°F, and croupy respirations were noted. Laryngotracheobronchitis was diagnosed. Acetaminophen, humidification, and fluids were prescribed.

Within two hours, the child was returned with a high fever. When respiratory difficulties were detected, a pediatrician was notified. A right

upper lobe infiltrate was identified on chest xray, and CSF testing led to a presumptive diagnosis of pneumococcal meningitis. The child was transferred to a regional medical center. Despite intensive support, the child died one week later with cerebral edema and uncontrollable increased intracranial pressure.

A subsequent malpractice claim alleged that a failure to properly diagnose and treat meningitis had resulted in the infant's death. Reviewers concluded that the care rendered was substandard, and, as they recommended, the claim was resolved through settlement.

COMMENTS

The providers in this case appear not to have acknowledged clear warning signs of a serious bacterial infection. The medical history alone should have raised concern. Also, listlessness and fatigue argued for the performance of a lumbar puncture, along with several other studies. Lumbar puncture of an infant should occur when there is:

1. suspicion of meningitis, especially after recent antibiotic therapy;
2. age less than two months and fever greater than 39°C;
3. toxicity or lethargy;
4. meningeal signs or bulging fontanelle;
5. seizure activity;
6. petechiae or purpura; or
7. poor muscle tone, grunting, cyanosis, or hypotension.[4,10, 11,12]

In the absence of other findings, a simple febrile seizure (single, brief and generalized) does not mandate a lumbar puncture. A large retrospective analysis of children with meningitis found that a simple febrile seizure alone was not a reliable indicator of serious bacterial infection. Ninety-three percent of children with simple seizure later diagnosed with meningitis were obtunded or comatose upon presentation. The remainder demonstrated meningeal signs with irritability.[13]

The appropriate use of diagnostic studies and specialty consultations is an important albeit difficult medicolegal responsibility of any primary care provider. One clinical decision that continues to be troublesome concerns the timing of lumbar puncture and neuroimaging. Current recommendations are that lumbar puncture be undertaken before scanning when delay would be dangerous to a patient's life and **ALL** the following are **ABSENT**:

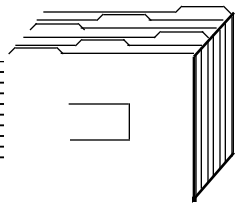
1. an altered state of consciousness
2. abnormal pupil size and reactivity
3. papilledema
4. generalized seizure activity
5. petechiae and purpura.[14]

The infant in Case 3 was repeatedly evaluated by the emergency department providers for similar but worsening complaints. On multiple occasions, the prevailing standards for pursuing diagnostic studies and specialty consultations were breached. The unplanned, unappointed return visit of a febrile infant to acute care providers should ring a "risk management" alarm and prompt a thorough re-evaluation.

FINAL COMMENTS

In the clinical context of pediatric bacterial meningitis and in light of these cases, certain advice regarding patient care and chart management appears warranted.

While maintaining the role of patient advocate, the provider must listen to parents carefully. A friendly attitude not only encourages parents to convey pertinent history but also avoids misunderstandings



PEDIATRIC BACTERIAL MENINGITIS, cont'd

and confrontations that could be detrimental to the child's care. A recent article discussed how value differences between health care providers and parents strongly influence the clinical assessment of a febrile child.[15] Parents emphasized the short-term pain and inconvenience of diagnostic testing. They were more willing to risk the remote chance of severe long-term morbidity. Physicians may construe this as a manifestation of parental scientific illiteracy, but they, in turn, are often considered by parents as blind to the emotional and other demands involved with raising children.

Pursue consultation. Although "knowing what one does not know" is a challenge, most experienced practitioners develop a keen sense of recognizing when they are in over their heads, and they act accordingly. If economic pressures within managed care are applied to discourage consultation, remind the managers that the cost of only a single claim for the delayed diagnosis of meningitis will dwarf the expense of many consultations with skilled specialists.

Third, provide the parents written instructions on discharge. Make sure they understand:

1. the seriousness of fever;
2. how to give fluids and treatments;
3. the symptoms that denote clinical worsening;
4. the need to call or return if worsening appears; and
5. when the child is scheduled for reevaluation.

The medical record of the clinical evaluation of a febrile child should clearly reflect that the diagnosis of bacterial meningitis was a consideration, if only remote, in the mind of the provider. Subjective factors like vomiting, feeding, fluids, irritability, activity, and consolability should be addressed. Objective findings like fever, vital signs, mental status, appearance, activity, neurologic function, and other pertinent physical findings should be recorded. The performance and results of diagnostic studies, specialty consultations, and treatments also deserve documentation.

In the future, the treatment of serious bacterial infections may be influenced by factors not evident in the three cases reported. Hib vaccines were first licensed in 1985, and the conjugate vaccine was approved for two-month-olds in 1990. Since that time, the nasopharyngeal carrier rate for Hib has decreased markedly. Between 1983 and 1991, invasive Hib has decreased by 90 percent in children less than five years old.[9] Thus, one of the key pathogens causing serious bacterial infections, meningitis and severe neurologic damage in young children has been significantly curtailed.

Strep pneumococcal nasopharyngeal isolates are becoming increasingly resistant to penicillin (26 percent in Alaska, and from 1 to 16 percent in the remainder of the United States in 1993).[16] The emergence of resistant strains highlights the need for an effective pneumococcal conjugate vaccine for children. Currently, oral therapy offers some protection against occult bacteremia caused by strep pneumococcus, while intramuscular antibiotics are required when Hib bacteremia is suspected.[8]

These and similar factors have clearly altered the diagnosis and treatment of pediatric bacterial meningitis and, consequently, will influence the rate and nature of medical malpractice claims involving the disease. True clinical success, with the prospect for a real reduction in liability, will continue to remain dependent, however, upon the skilled provider comprehensively evaluating the febrile child and diligently considering whether serious bacterial infection or meningitis could be present.

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LEGAL DUTIES INVOLVING PHYSICIANS, PATIENTS AND THIRD PARTIES: PART TWO

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TARASOFF

In 1973, a malpractice case that had been initially dismissed by a California trial court eventually triggered a medicolegal earthquake. Prior to that time, physicians were occasionally sued when their patients injured third parties through contagious disease or reckless driving.[1] *Tarasoff* has become generic, like Xerox™ to photocopy, for a malpractice case that arises after injury to a third party by a different category of dangerous patient.[2,3,4] It has added a completely novel dimension to physicians' duty to non-patients.

Tatiana Tarasoff was stabbed and shot to death on the porch of her Berkeley, California, home on October 27, 1969. Her killer, Prosenjit Poddar, a University of California student from India, had become romantically obsessed with Tarasoff. He was also pathologically jealous. Having kissed Tatiana once, considered the equivalent of betrothal in his native culture, he became extremely upset when he witnessed her kiss others. Poddar taped his telephone conversations with Tatiana and replayed them continuously, searching for clues of her affection.

At the urging of a friend, Poddar was evaluated by a Student Health Service psychiatrist who determined that hospitalization was not indicated, prescribed a neuroleptic, and referred him for outpatient psychotherapy with a psychologist. During psychotherapy, Poddar acknowledged violent fantasies about Tarasoff, who was temporarily out of the country. He related that he might kill her when she returned. Poddar's friend informed the psychologist that his patient had purchased a gun. The psychiatrist and psychologist conferred and agreed that Poddar should be hospitalized for further evaluation, against his will, if necessary. They concluded that he was suffering a severe, acute schizophrenic reaction. Unaware that the state law regarding involuntary hospitalization had recently been changed and convinced that he was following proper procedure, the psychologist asked the campus police to apprehend the patient and escort him to the hospital for involuntary evaluation. On August 20, 1969, the campus police interviewed the patient and determined that he was behaving normally and rationally. They exacted a promise that he would not harm Tarasoff.

Poddar never returned to the Student Health Service. He killed Tarasoff shortly after she returned to the United States. Arrested and tried for homicide in the first degree, he was convicted of second degree homicide. That conviction was ultimately overturned on a technicality, and Poddar returned to India.

Tarasoff's parents sued the University of California, the professionals involved, and the campus police. They alleged a negligent failure to hospitalize their daughter's killer. Almost as an afterthought, they also claimed a "failure to notify" them that their daughter was in grave danger.

The parents' suit was initially dismissed. On appeal, an intermediate court affirmed the dismissal after concluding that there was no statutory duty requiring any of the defendants to hospitalize Tarasoff's killer; that the length of time between the attempted hospitalization and the murder was too long to support proximate cause; that the defendants held statutory immunity for discretionary acts; and that, most important for this discussion, the defendants

LEGAL DUTIES . . . PART TWO, cont'd

owed no legal duty to the Tarasoffs or their daughter because there was no special relationship between them. One judge strongly dissented, however, and argued that a legal duty to warn existed and provided support for a cause of action.

Echoing that dissent, the California Supreme Court, after hearing the case on appeal in 1974, overturned the dismissal. Noting that the defendants could not escape liability merely because the Tarasoffs were not their patients, the court held that "[w]hen a doctor or psychotherapist, in the exercise of his professional skill and knowledge, determines, or should determine, that a warning is essential to avert danger rising from the medical or psychological condition of his patient, he incurs a legal obligation to give that warning." Quoting from another case, the court stated: "The assertion [of the defendants] that liability must be . . . denied because defendant bears no 'duty' to plaintiff begs the essential question whether the plaintiff's interests are entitled to legal protection against the defendant's conduct . . . ." The court dealt further blows to the defense by emphasizing that their special relationship with a dangerous patient was reason enough to impose that duty.

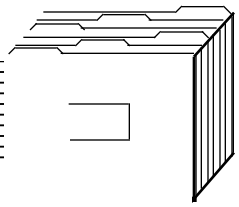
> [A] patient with severe mental illness and dangerous proclivities may, in a given case, present a danger as serious and as foreseeable as does the carrier of a contagious disease or the driver whose condition or medication affects his ability to drive safely. We conclude that a doctor or a psychotherapist treating a mentally ill patient, just as a doctor treating physical illness, bears a duty to use reasonable care to give threatened persons such warnings as are essential to avert foreseeable danger arising from his patient's condition or treatment.

The court followed a common law principle that an obligation of due care attaches when one voluntarily undertakes to help another. In the opinion of the court, the defendants' efforts to have the killer committed amounted to helping Tatiana Tarasoff. The court also referred to another common law principle that a person whose action causes another to be in danger must give warning to the other. The acts of the psychologist and campus police led Poddar to abruptly discontinue therapy, increasing the danger to Tarasoff. The court dismissed the defendants' argument regarding difficulties with and inaccuracies in predicting patients' future dangerousness. The opinion emphasized that, minimally, the defendants had expressed grave concern about the potential for harm to Tarasoff, the very reason they attempted the involuntary hospitalization of Poddar.

In 1976, the California Supreme Court uncharacteristically agreed to rehear arguments regarding the duty to warn issue.[4] The rehearing followed persistently expressed concerns by the American Psychiatric Association that requiring such a warning could severely compromise doctor-patient confidentiality, a crucial basis and an ongoing support for effective psychotherapy.

The court modified its 1974 duty to warn, subsuming it under a broader duty to protect. In the 1976 opinion, *Tarasoff II*, the court stated:

> [O]nce a therapist does, in fact, determine or under the applicable professional standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger. While the discharge of that duty . . . will necessarily vary with the facts of each case, in each instance, the adequacy of the therapist's conduct must be measured against the traditional negligent standard



LEGAL DUTIES . . . PART TWO, cont'd

of the rendition of reasonable care under the circumstances.

The court noted that the duty to protect might be discharged in various ways, such as issuing a warning to the intended victim "or others likely to apprise the victim of the danger," notifying police, or initiating "steps reasonably necessary under the circumstances."

The defense had reiterated an argument that a lack of warning was justified because of the legal obligation to respect doctor-patient confidentiality. The court replied "that the public policy favoring protection of the confidential character of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others. The protective privilege ends where the public peril begins." Furthermore, the court noted that the California Evidence Code specifically waived the statutory psychotherapist-patient communication privilege when disclosure was required "to prevent threatened danger."

Addressing psychiatry's concern about the poor predictive value of clinical determinations regarding potential for violent behavior, the court declared that any unreliability in prediction does not negate a duty to protect. It considered the risk of unnecessary warnings a reasonable cost for saving potential victims. At the same time, the court discouraged rote disclosures of all threatening comments, apparently unaware of the serious problems that would arise clinically when practitioners tried to walk the tightrope of this newly minted legal standard.

So powerful was the response to *Tarasoff* by psychiatrists across the country that many believed the California case applied nationally. As late as 1984, Givelber and his coauthors reported that approximately 90 percent of psychiatrists they surveyed were aware of *Tarasoff*.[5] Most, however, incorrectly believed their legal duty to potential victims was specifically to warn them, rather than to act reasonably to protect them. Clinicians, focusing on the particular facts of *Tarasoff*, where a warning was at issue, apparently failed to appreciate the broader legal standard enunciated.

Tarasoff left a number of issues unclear, one of which concerned the breadth of the duty to protect. In *Thompson v. County of Alameda*, the California Supreme Court subsequently limited the duty to protect to those third parties who were reasonably foreseeable and ***identifiable*** as potential victims at the time of the patient's threat.[6] The case involved a violent, institutionalized juvenile offender who was known to harbor dangerous impulses to harm young children. He had threatened, once discharged from the institution, to murder some unidentified child in his neighborhood. Neither the mother of the juvenile offender, nor anyone else, was warned of this threat when he was released to her custody. Shortly thereafter, he murdered a five-year-old child who lived nearby. The parents of the victim sued the county for having failed to warn them. The court held that a victim, if not named, must be identifiable and that a generalized threat to the public-at-large or a segment thereof would not support an affirmative duty to warn.

Despite the limit imposed by *Thompson*, *Tarasoff* left the medical community, especially psychiatry, in an uproar. Worrisome issues remained: what is adequate to insure protection; what effect will a breach of confidentiality have on a patient's willingness to continue psychotherapy; what is "reasonable" when determining who might be a foreseeable victim; how does one meet illusory professional standards of danger assessment; how much control can be exerted over a patient; does informed consent require a patient to be advised of the psychiatrist's duty to protect others; and how would other states

react to *Tarasoff*? Some of these have been addressed in subsequent cases and with legislation.

POST-*TARASOFF* TRENDS

Early Cases

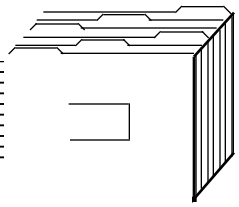
New Jersey seized the baton in 1979 and agreed with *Tarasoff* that there is a legal duty to protect third parties and that confidentiality is not absolute.[7] Referring to earlier cases that involved the duty of a physician to warn or protect third parties from patients' contagious diseases and also relying heavily on *Tarasoff*, the court held:

> . . . that a psychiatrist or therapist may have a duty to take whatever steps are reasonably necessary to protect an intended or potential victim of his patient when he determines, or should determine, in the appropriate factual setting and in accordance with the standards of his profession established at trial, that the patient is or may present a probability of danger to that person. The relationship giving rise to that duty may be found either in that existing between the therapist and the patient, as was alluded to in *Tarasoff II*, or in the more broadly based obligation a practitioner may have to protect the welfare of the community, which is analogous to the obligation a physician has to warn third parties of infectious disease. . . . To an admittedly uncertain but nevertheless sufficient extent, 'dangerousness' must be considered identifiable . . . and although not a 'disease' as that term is commonly used, may affect third persons in much the same sense as a disease may be communicable.

The court noted that terms such as duty, dangerous, dangerousness, reasonableness, and beauty all have abstract qualities and "may be difficult or impossible to define in absolute and precise terms, even when applied to specific facts." The court also implied that psychiatrists historically had both assessed and predicted patients' behavioral qualities and, therefore, should not complain they were being unfairly burdened. The specific facts in the New Jersey case were elaborate, tortured, and highly controversial. Nevertheless, an expert witness had testified convincingly that the defendant physician was grossly deviant in failing to warn an identifiable victim of a clearly dangerous patient.

In another case, a federal district court held that Nebraska law required a psychotherapist to "initiate whatever precautions are reasonably necessary to protect potential victims of his patient . . . when, in accordance with the standards of his profession, the therapist knows or should know that his patient's dangerous propensities present an unreasonable risk of harm to others."[8] The case created a stir because the opinion articulated a duty to protect when, under the factual circumstances, no victim could have been identified.

A patient had undergone inpatient psychiatric treatment followed by day-hospital care at a Veterans Administration medical center. After purchasing a shotgun, a fact unknown to the hospital staff, the patient withdrew from the day-hospital program against medical advice. A month later, he fired the shotgun into a crowded nightclub, wounding the plaintiff and killing her husband. No threats toward nightclub patrons had been voiced, although the patient, when disgruntled, had uttered generalized threats that were not considered serious by the medical staff.



LEGAL DUTIES . . . PART TWO, cont'd

The plaintiff alleged that the VA knew or should have known of the patient's dangerousness and that he should have been involuntarily hospitalized. Because the case was settled out of court, it is impossible to analyze how the district court judge would have dealt with the specific facts of the case, in light of the expanded duty referenced. The court did state that no liability would be imposed upon a physician who, using due care and proper professional techniques, allows his patient the freedom of a less restrictive environment and injury to a third party results. The court also noted that, because psychiatric assessment necessarily involves some degree of uncertainty, negligence "may not ordinarily be found short of serious error or mistake . . . ."

Reviewing post-*Tarasoff* decisions, one legal commentator argued that foreseeability had become the pivotal issue.[9] Courts held physicians liable only when the injured party was known to the physician or known to be close to the object of violence. Further, threats were specific, and the patient's history was replete with dangerous behavior that had been overlooked or improperly discounted. Courts had not held physicians liable when, at the time of assessment, a patient posed no realistic threat to any identifiable individual. In 1982, a federal court in *Hasenei v. U.S.* found VA physicians not liable for failing to protect motorists who suffered injuries when one of their patients, acutely alcohol intoxicated, crashed head-on into another car in an apparent homicide/suicide attempt.[10]

The patient, while on active duty, had been treated at an Army medical center for severe alcoholism and paranoid schizophrenia. At that time, he acknowledged both suicidal and homicidal thoughts. Having improved significantly, he was transferred to a Veterans Administration hospital near his home in Pennsylvania for transitional care prior to a medical separation from the military.

Following a brief but unremarkable hospitalization, the patient was discharged to outpatient care. For unknown reasons, he did not attend the outpatient clinic for four months, three months later than planned. He then reported that his son had been killed in the interim. Having blamed himself, the patient further reported that he had begun drinking intermittently but not heavily. This history was supported by the patient's wife in conversations with the hospital's social services personnel. The patient subsequently described, however, a number of concurrent successes in his life, and he expressed hope for an improved future. No suicidal or homicidal ideation was evident. The psychiatrist changed the patient's neuroleptic medication and scheduled a follow-up appointment in one month. Days later, the man committed suicide in a vehicular crash that injured others. The injured victims sued the federal government.

The plaintiffs alleged foremost that VA physicians had negligently failed to hospitalize or, in some other manner, control the patient. Applying Pennsylvania law, the federal district court concluded that the VA physicians owed no legal duty to the motorists, because they had no legal right or ability to control the patient. The court stated that control was simply a special form of protection and that common law principles still applied: there is no duty, in the absence of a special relationship, to control another.

The district court noted, somewhat critically, that no court recognizing a *Tarasoff* duty had ever indicated what was intrinsic to the doctor-patient relationship that made it "special" and thereby legally granted the doctor either the right or the ability to control a patient. The usual doctor-patient relationship, especially one involving an outpatient, does not involve control. Relationships that involved control were exemplified by parents and children, masters and servants, land

owners and licensees, and persons officially responsible for those with dangerous propensities, such as prison authorities with regard to convicts. The court found no similar relationship in the case under consideration. Moreover, the patient in question never met Pennsylvania standards for involuntary commitment, from which a duty for the psychiatrist to take control of the patient might have been derived.

The plaintiffs also argued that the VA physicians should have prevented the patient from driving, because he was a known alcoholic who had expressed suicidal thoughts in the past. The court dismissed this argument, given the facts proven in the case and the judge's conclusion that there was nothing that the physicians could have done to prevent the patient from driving.

This federal court was unwilling to accept *Tarasoff*. The court appears to have been more receptive to arguments regarding limitations on the ability of psychiatrists to predict future rather than imminent dangerousness. In that context, a lack of foreseeability can eliminate the element of proximate cause necessary to prove negligence. Courts in Maryland and Florida have also affirmatively rejected *Tarasoff*.

Other Jurisdictions

In a federal case from Kansas, later affirmed by the United States Court of Appeals for the Tenth Circuit, a jury held hospital physicians liable for the death of a patient's parents.[11] The patient had been hospitalized after threatening his grandparents, with whom he lived. After three months, he was discharged with a diagnosis of passive-aggressive personality and sociopathic tendencies. He was sent to another state to live with his parents. One week later, he murdered them.

The estate of the parents sued for negligent release of the patient from the hospital. Addressing questions certified by the federal appellate court, the Kansas Supreme Court declared negligent release of a patient with violent propensities a valid cause of action for malpractice. In so doing, the court sidestepped whether a duty to warn or protect third parties existed in Kansas under circumstances involving a potentially dangerous patient. The court indicated that third parties have a right to be free of injury that arises from a physician's malpractice, a clear departure from the generally accepted limitation of such a right to those, as patients, who are under the doctor's direct care. Earlier cases allowed for liability to third parties premised upon either a duty of ordinary care or a duty arising out of a special relationship, but not one emanating from simple negligence on the part of a doctor.

The Kansas opinion leaves unclear how a duty to avoid injuring patients by substandard medical care evolves into a duty to non-patients. The duty to a patient is distinguishable, however, from the duty to non-patients, because the duty to third parties requires a physician to take affirmative action outside the usual course of medical care to protect them. The closest the court came to justifying this opinion was to quote at great length prior cases involving infectious diseases that recognized a physician's legal obligation to the public at large.

In summary, Kansas has acknowledged a cause of action, sounding in professional negligence, for the wrongful release of a dangerous patient, already under a physician's control, who subsequently injures a third party. The third party need not be identifiable, and the patient need not have made threats specific to the person injured. In this context, foreseeability appears to mean that, when a patient makes a general threat to harm someone, anyone in the world who is later injured can file suit.

LEGAL DUTIES . . . PART TWO, cont'd

The Supreme Court of Vermont faced the *Tarasoff* challenge in 1985.[12] A 29-year-old mental health clinic patient expressed a desire to seek revenge for a past rejection by his father. When asked about a plan, he mused that he could always burn down his parents barn, a structure located approximately 130 feet from his parents' house. After discussing the consequences of such an act with his counselor and promising not to burn the barn, the patient left the clinic. His counselor did not discuss this interview with her supervisors. The next night, the patient burned the barn. The parents sued the clinic for their property loss and alleged malpractice by the counselor in failing to take reasonable steps to protect them from their son.

The case was eventually dismissed by a trial court on the basis that there was no such duty to protect in Vermont. On appeal, the Vermont Supreme Court reversed, holding that such a duty did not differ substantially from legal obligations to warn in order to protect the public health. The defendants had cited *Hasenei v. U.S.* to support their argument that a counselor lacks sufficient control over an outpatient to support a duty to third parties.[10] The court rejected this, echoing *Tarasoff* that the relationship between therapist and patient is enough to create a duty to protect. The defendants argued further that the counselor had made a good faith assessment of her patient's intent and that she should not be held liable for a simple error in judgement.

The Supreme Court agreed, however, with the trial court's conclusion that the counselor had not acted as a reasonably prudent counselor, because she not only acted on inadequate information but also failed to seek consultation. The court concluded "that a mental health professional [defined by Vermont as a physician, psychologist, social worker, nurse, or other qualified person designated by the commissioner] who knows or, based upon the standards of the mental health profession should know that his . . . patient poses a serious risk of danger to an identifiable victim has a duty to exercise reasonable care to protect him . . . from that danger."

Historically, arson has been treated as a very serious crime, because it poses great risk of bodily harm. In this case, however, and unlike all other reported third party cases, no person was injured. Therefore, in Vermont, the danger to be warned of, and from which plaintiffs are to be protected, is not a danger to the victim's person, as *Tarasoff* implied, but to the victim's property interest! No other jurisdiction has followed Vermont's example.

In a Wisconsin case, a husband and daughter sued the psychiatrist of their bipolar wife and mother for medical negligence that they alleged had substantially contributed to an auto accident that caused the death of the patient, as the driver, and paralyzed the daughter.[13] They claimed that the psychiatrist had failed to timely diagnose, commit, or properly medicate the patient and that there was a failure to warn the family about both her dangerous psychotic condition and the adverse effects of her medication.

On appeal from a dismissal of the case, the Wisconsin Supreme Court granted the plaintiffs a cause of action, because: (1) a psychiatrist could be held liable for failing to warn about the side effects of medication adversely affecting driving ability, given the foreseeability of injury to both the patient and third parties; and (2) a physician has an affirmative duty to warn or to institute commitment proceedings to protect nonpatients even if threats are not directed toward an identifiable "target."

LEGAL DUTIES . . . PART TWO, cont'd

Confidentiality must yield to public safety. Warnings can be made to family members or to the police, but commitment of a mentally ill and dangerous patient may be the only effective recourse for the psychiatrist. The court recognized that the relative unlikelihood of an injury resulting from the alleged negligent behavior might, in a particular case, preclude the imposition of liability on a public policy basis (e.g., fairness, limiting litigation). Stated differently, proximate cause might not be demonstrable and, therefore, negligence would not be proven. This opinion is noteworthy, because the affirmative duties to warn and to protect by involuntary hospitalization are recognized for the sake of third parties.

North Carolina, on the other hand, has decided not to impose an affirmative duty on physicians to seek involuntary commitment of dangerous patients for the protection of third parties.[14] Providers cannot be held accountable for third party injuries inflicted by a patient who is voluntarily committed because they are not granted legally sufficient control over such a patient to support the imposition of liability. Once a patient is hospitalized involuntarily, however, and the staff has the legal power to restrain, negligent failure to do so can result in liability for third party injuries.

In the cited case, the court noted that, even if North Carolina subscribed to a duty to warn, that duty would not extend to a third party already aware of the patient's violent tendencies or to an individual unidentified by the patient as a potential victim.

Florida: Anticipating the Future

Recently, an appellate court in Florida determined that the state's confidentiality statute, in force when the case under consideration arose, barred the imposition of *Tarasoff*.[15] One judge on the appellate panel warned, however, that it would be "premature for us to express any view on the existence and scope of any duty", in light of amendments to the state's law that had been enacted in the interim.

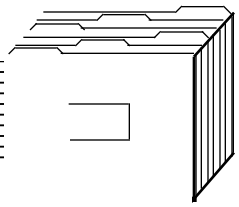
A young man had been killed by a psychiatric outpatient. The victim's father sued the psychiatrist and alleged negligent failure to hospitalize or to prescribe proper medications for the patient. He also alleged that the defendant had failed to warn the deceased, his parents or the police that the patient was prone to violence and had threatened the victim with serious harm. The complaint listed no specific threats because the psychiatrist, referring to Florida law that prohibited disclosure of confidential psychotherapist-patient communications, had refused to release the patient's records. Nevertheless, the plaintiff alleged, in accordance with *Tarasoff*, that the psychiatrist knew or should have known that the patient had threatened to harm the victim and that the psychiatrist's negligence had proximately caused the victim's death.

The court rejected the "enlightened" [sic] *Tarasoff* approach and the cases from other jurisdictions that had followed California. The court stated that:

1) Florida law, in the absence of a special relationship, imposes no duty to control another's behavior or to warn endangered third parties;

2) a special relationship must include the ability or the right to control;

3) the relationship of a psychiatrist and a voluntary outpatient lacks the necessary elements of control;



4) a duty to control cannot be transformed into a duty to warn or protect;

5) such a transformation would impose an unreasonable duty on psychiatrists, psychologists, psychotherapists, and "other mental health practitioners";

6) it is unfair to impose such a duty because psychiatry is an inexact science characterized by wide disagreement among practitioners regarding diagnosis, treatment and the likelihood of future dangerousness;

7) it is virtually impossible to reliably or accurately predict dangerousness;

8) "to impose a duty to warn or protect third parties would require the psychiatrist to foresee a harm which may or may not be foreseeable, depending on the clarity of his crystal ball . . . . [I]t would be fundamentally unfair to charge a psychiatrist with a duty to warn";

9) imposing a duty to warn would "wreak havoc with the psychiatrist-patient relationship", the cornerstone of which is confidentiality; and

10) Florida law prohibits the disclosure of confidential psychiatrist-patient communications to third parties.

A critical dissenting opinion, similar to that in the initial appeal of *Tarasoff*, includes the following:

> The court says that, no matter what the underlying circumstances, no matter how great the danger, no matter how trivial the effort required to prevent the harm, no matter what the proof concerning the likelihood that even a phone call might have saved the human life, no jury could properly hold Dr. Burglass civilly responsible. I cannot agree with a conclusion which seems to me to be so contrary to the requirements of a civilized society and therefore to what should be the standards of our law.

After the case commenced, but prior to its resolution, the Florida legislature enacted a statute that, when a patient being treated by a psychiatrist made an actual threat to physically harm an identifiable victim, and a threat which, in the clinical judgement of the psychiatrist, the patient is capable of and will more likely than not carry out in the near future, "the psychiatrist ***may*** disclose patient communications ***to the extent necessary to warn*** any potential victim or . . . law enforcement agency." [emphasis supplied.] The dissenting justice in *Boynton* argued that the newly enacted statute merely reflected Florida's preexisting public policy supporting the imposition of a legal duty to warn. The majority dismissed his argument and emphasized that the permissive "may" in the statute was aimed at immunizing psychiatrists from liability for a breach of confidentiality in circumstances where the psychiatrist's best judgement raised a moral duty to warn. Recall that other courts have concluded that once a psychiatrist makes such a clinical judgement, a legal duty arises to warn or protect.

In a law review article highly critical of the Florida decision, the author concluded that "the court improperly reached its results by taking improper judicial notice of marginally relevant, outdated, and controversial research regarding the state of modern psychiatry."[16] He referenced alternate research supporting "a substantially more optimistic view of psychiatry's prediction of dangerousness." Therefore, foreseeability of injury is indeed reasonable. Furthermore, preexisting Florida legislation authorized psychiatrists to involuntarily hospitalize patients based on a finding of mental illness with dangerousness.

This commentator noted that the state relies upon psychiatric evaluations for granting bail bonds, authorizing purchase of firearms, and sentencing criminals. The courts have regularly held members who practice "inexact science" liable for malpractice, indicating that standards do exist and that sufficient "exactness" can be determined to allow liability to be imposed on the basis of public policy and fairness. Moreover, medical practice involving infectious diseases, such as tuberculosis, is not as exact as the Florida court postulated, and "certainty" has never been a required legal basis for imposing liability.

Lastly, the author criticized the opinion's analysis of control and confidentiality. Most physicians who diagnose and treat contagious diseases have little control over their patients. Florida case law arguably allowed a broader definition of control than did the court. The Florida court neglected studies demonstrating that laws requiring physicians to breach confidentiality to meet a duty to warn had little effect on the access to or provision of psychiatric treatment. In addition, Florida law need not and should not be read as demanding an unyielding right of confidentiality.

Considering the conflicting opinions in *Boynton,* as well as the scholarly criticisms generated in its wake, one would be pressed to accurately predict the future reception of *Tarasoff* in Florida.

LEGISLATION

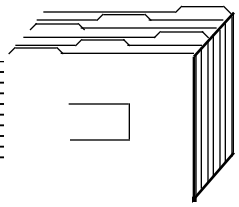
Currently, at least ten states have enacted specific statutes that address the duty to warn third parties about, or protect them from, a behaviorally dangerous patient.[17] Generally, these laws require that a patient must communicate a threat to a mental health care provider, and they immunize the provider from liability for a breach of confidentiality. The laws differ with regard to who owes the duty to protect, the type of threats that give rise to the duty, the identifiability of the victim, and the manner or criteria by which the duty is discharged.

All these statutes impose a duty on psychologists, but, interestingly, the Minnesota law does not specify psychiatrists. The duties of nurses, social workers and "professional counselors" are delineated in some statutes. Indiana and Colorado impose the obligation to protect upon certain legal entities, such as college counselling centers and community mental health centers.

Uniformly, the laws require that there be an utterance or some behavior on the part of a patient that constitutes a threat of physical violence to another individual. Some require that the threat be "serious", the violence "imminent, or "specific means" for bringing about the injury be communicated. The standard for victim identification ranges from "reasonably identifiable" (most states) to "clearly identified." Each of these laws also mandates the actions required to discharge the duty, including the means by which potential victims and law enforcement officials are to be notified.

FINAL THOUGHTS

By court decision and legislation, the law, following the lead of medicine, seems to view the psychiatric patient as special. This viewpoint undoubtedly reflects a number of social, cultural and historical beliefs, even biases. Judicial opinions analogize and distinguish between patients made dangerous by their mental illness and those who are dangerous by virtue of other medical conditions. The law, in certain circumstances, has expanded the duty of health care providers to protect third parties while narrowing it in others.



One medicolegal expert has stated that, although both law and medicine "agree that society deserves protection from violence and that breaching psychotherapist-patient confidentiality is sometimes necessary, there is little consensus about the most effective manner in which to protect third parties."[9] As a result, mental health providers find themselves afloat in a sea of legal chaos, potentially held liable by a system that can be both arbitrary and unfair.

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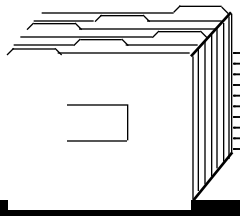

LEGAL MEDICINE

CONSULTANT'S CORNER

APPROACH TO THE ACUTE RED EYE PATIENT

by WILLIAM C. LLOYD, III, M.D., F.A.C.S.
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The acute care of an eye disorder is occasionally the subject of a malpractice claim but more often becomes the nexus of other interaction between law and medicine, e.g., personal injury or workers compensation claims. A practicing Board certified ophthalmologist, who is also a Diplomate of the American Board of Pathology, addresses a common yet problematic eye condition that periodically challenges every primary care provider.

One of the most common ocular complaints encountered by non-ophthalmologists is the acute red eye. Fortunately, the patient is usually experiencing mild ocular inflammation related to a superficial problem such as a conjunctivitis, corneal abrasion, or foreign body. All primary care and emergency medicine providers should be familiar with those techniques involved in performing a basic screening eye examination. The goals of the health care provider who is not an ophthalmologist are to correctly diagnose and treat lesser problems, while identifying the more serious conditions that can threaten vision. An acceptable baseline eye exam does not require $200,000 worth of exotic equipment, demand a laser, or command fluency in those indecipherable abbreviations used by ophthalmologists.

In the military health care system, most physicians will be provided the opportunity to evaluate red eye patients. This article offers practical guidance in the evaluation, diagnosis and management of the acute red eye patient. It is not meant to be an exhaustive treatment of common eye disorders.[1] The information presented is intended to help clinicians identify key elements of a good emergency eye exam and emphasizes common problem areas and preventable errors.

Ophthalmology residents are initially taught three basic rules for a good eye examination: visual acuity, visual acuity, and visual acuity. If you recall anything from this article remember this: ***Always measure the patient's visual acuity and always document visual acuity in the medical record***. Some might feel offended by this simple advice - eyes, eye symptoms, visual acuity - it's automatic, right? One wishes it were, but all too often patients with eye complaints are evaluated and treated with no recorded visual acuity (even in ophthalmology clinics!).

No single piece of information from an eye examination is more valuable than visual acuity. Neglecting to record the vision creates two kinds of problems, clinical and legal. First, without a recorded visual acuity there is no clinical baseline against which to measure vision on follow-up. Secondly, patients may claim that the initial vision was anywhere between 20/20 and ***total blindness***. I have seen multiple imaginative permutations of this assertion, to include longstanding NLP (no light perception) patients and their attorneys who insist that astronaut-quality vision was enjoyed until the moment of

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ACUTE RED EYE PATIENT, cont'd

arrival at the emergency room with a red eye. Similarly, years ago I was deposed during a civilian employment compensation case in which the individual claimed a blinding job site injury, until it was revealed that records from prior military service confirmed the presence of low vision from childhood due to strabismus. Use your imagination.

Having belabored that point, I offer a few practical tips about measuring vision. If the patient normally wears spectacles to drive, they should be worn when vision is tested. If the experience of ophthalmologists holds true, the spectacles will have been left in the car. Ask that they be retrieved. Without glasses, visual acuity can be tested with a pinhole occluder or an index card fenestrated with multiple small holes. Measure one eye at a time, right eye first by convention. Note in the chart if the patient was using the full spectacle correction, a pinhole, or no correction.

A 20 foot lane with an official Snellen (Big E) chart is not necessary to document vision. Improvised charts include clocks, newspaper headlines, or posted signs - but be careful to jot down the height of the letters and the distance from which they were visible. Reading vision (magazines, telephone books) at 14 inches can be an effective substitute, as long as you remember that patients over age 40 will likely need reading glasses for regular print at that distance. For severe visual loss, rely on finger counting and hand waving. Do not restrict your attempts to measure vision to cooperative, able-bodied, easily evaluated adults. Bedridden patients, the illiterate, those who speak a language other than English, and children, including infants, should undergo vision testing.

The acute red eye history can be reduced to a few questions, for example, “Are you having the problem in one or both eyes?” or “What were you doing when you first noticed the symptoms?” Discriminate between eye **pain** (i.e., that caused by acute glaucoma, uveitis, corneal abrasion, episcleritis), **discomfort** (dry eye, foreign body), **discharge** (conjunctivitis), or an asymptomatic **injected globe** (subconjunctival hemorrhage). Pertinent facts that deserve notation in the record include prior eye conditions and treatments, ocular medications, family eye history, recent trauma, and the patient’s general medical condition. Do not forget to ask about contact lenses. Contact lens overwear is a very common and easily overlooked diagnosis. [Ancient Ophthalmology Proverb - ***If you do not look, you will never see.***]

Once the visual acuity is measured, perform an external, gadget-free examination. Symmetry is fundamental. Differences between eyelid position, pupil size and reactivity, corneal clarity, iris color, and extraocular motility can signal very serious conditions.

Palpate for preauricular and cervical adenopathy; they frequently implicate nonbacterial infectious conjunctivitis. Evert the lower eyelids to examine the tarsal conjunctiva. Allergic conjunctivitis (usually bilateral) often produces flat cobblestone papillae, whereas a viral process (unilateral or markedly asymmetric) yields dome-shaped conjunctival follicles. True bacterial conjunctivitis (frequently bilateral) produces a copious, thick, purulent discharge, while other pathogens cause more watery or stringy exudates. Eversion of the upper eyelid is easily learned and essential in searching for foreign bodies.

As you jot down your findings, avoid “ophthojargon”. You are not auditioning for a residency in eye surgery, and there can be minefields. Did you mean Hutchinson’s sign, Hutchinson’s triad, or Hutchinson’s pupil? More than once I have discovered PERRLA (pupils equally round and reactive to light and accommodation) decorating medical record of a monocular

ACUTE RED EYE PATIENT, cont'd

patient. Could there be a faster way to undermine the credibility of your written observations? When something appears normal, write “normal”.

Episodes of acute glaucoma are fairly straightforward. First of all, the patients are quite ill. As a consequence of their marked rise in intraocular pressure, many have vomited while waiting to be evaluated. Penlight examination often discloses a grey or cloudy cornea and a mid-dilated pupil that reacts sluggishly. Finger palpation to assess intraocular pressure is helpful only in the most severe cases. An easily used, handheld tonometer is preferable.

Most patients complaining of acute eye pain have irritated corneal nerves. You will provide significant temporary relief with a single drop of topical anesthetic. This will also provide you valuable time to complete your examination. One word of caution. Patients have been known to smuggle anesthetic for home use, and the medication is toxic to the corneal epithelium.

Apply fluorescein to the cornea and illuminate the surface with a cobalt blue light to highlight epithelial defects (abrasions, dendrites, exposure, etc.). Many providers have been trained to remove superficially embedded foreign bodies under a slit lamp. Remember, the thickness of the central cornea is only 500 micra. You may successfully excavate the particle only to create a leaking perforation. Select these cases carefully. Rely on a small gauge (#23 or #25) needle on a 5cc syringe as your instrument when choosing to persevere. If you have any hesitation, patch and refer to the nearest ophthalmologist.

Another caution. Are you sure there is only **one** foreign body? Here is a lesson that cannot be overemphasized. Entry wounds in the periorbital skin, eyelids, conjunctiva or globe from small, high velocity particles are easily overlooked. Sterile intraocular media and intraorbital tissues are ideal culture material for contaminated, retained foreign bodies.

Immediate ophthalmological consultation is obligatory in some acute red eye situations: hyphema (blood inside the anterior chamber), intraocular foreign bodies, and any suspected or confirmed penetrating injury of the globe. An eye shield and prompt referral are recommended. These are the cases where expediency may directly affect final visual outcome. During transfer, the penetrated globe should receive no topical medications, especially ointments.

The majority of red eye cases satisfactorily recover in a few days. It is, however, impossible to predict those patients who will experience a stormy clinical course. Universal follow-up instructions should include discussion of four Ps: **P**ain that increases or is not relieved with aspirin or acetaminophen; **P**us; **P**ink — progressive or persistent globe hyperemia; and, **P**oor vision. If the eye does not begin to feel better, look better, and see better, it’s time for another exam.

Some final advice is warranted. Patients treasure vision, and they respond to eye problems differently. As a generalization, patients with ophthalmic disorders are concerned about the prospect of losing eyesight. The clinician often can foster compliance with a clear provision for timely follow-up, should the problem persist.

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THE ACUTE RED EYE PATIENT
TEN STEP CHECKLIST

1. Always record the best corrected visual acuity.
2. Use simple descriptive terminology in the medical record.
3. Conjunctivitis is most commonly painless.
4. Is the patient wearing contact lenses?
5. Trauma may involve more than one foreign body.
6. Do not diagnose glaucoma without measuring the intraocular pressure.
7. If the eye needs steroids it needs an ophthalmologist.
8. Have the patient gaze at a distant target for a reliable pupil exam.
9. Never patch a suspected penetrating globe injury.
10. Remind the patient of the 4 P's.

MEDICOLEGAL GRAND ROUNDS - MISDIAGNOSES INVOLVING PREGNANCY

by FRANK T. FLANNERY, M.D., J.D.
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Amenorrhea is a symptom commonly reported not only to practitioners of obstetrics and gynecology but also to internists, family practitioners, and other primary care providers. Current technology enables providers to more accurately diagnose pregnancy and estimate its stage. Nonetheless, both the failure to diagnose pregnancy and the inaccurate estimation of gestational age continue to spawn litigation.

Several years ago, the Supreme Court of Mississippi considered the case of a 34-year-old woman who presented to her physician with urinary frequency, back pain, and a five-month cessation of menses.[1] Tetracycline and Bactrim DS™ were prescribed. Several weeks later, the patient complained of pelvic tenderness. Diagnosed with a vaginal infection, she was prescribed Flagyl®. During several subsequent visits, the patient complained of swollen feet, breast tenderness, back pain and bloating. A diuretic and a semisynthetic penicillin were additionally prescribed.

During the months following her initial visit, the woman was evaluated by her physician eight times. Pregnancy was never diagnosed. Two weeks after the final visit, she experienced severe abdominal cramping and delivered a stillborn infant.

The patient sued, claiming that her physician failed to perform an adequate physical examination or order readily available laboratory tests. She maintained that this conduct represented negligence, resulting in the prescription of teratogenic medication and her unborn child's death.

The Mississippi Supreme Court reversed an initial summary judgment for the defendant doctor and remanded the case for further disposition. Among other determinations, the court found that

the affidavit of the patient's medical expert should have been more seriously considered. The expert contended that the defendant physician had arrived at an irrational diagnosis, unsupported by physical examination or laboratory evidence.

Failure to detect an ectopic pregnancy also continues to result in professional liability claims. In a recent case, a patient with an intrauterine device experienced prolonged menstrual bleeding and discomfort.[2] After removing the device, her doctor prescribed antibiotics for a presumptive diagnosis of pelvic inflammatory disease. The results of a subsequent serum pregnancy test were positive, and a sonogram demonstrated a small uterine lucency suggesting an early gestation. A subsequent sonogram did not demonstrate a gestational sac.

Three weeks following the diagnosis of probable intrauterine pregnancy, the patient was hospitalized for severe abdominal pain. An exploratory laparotomy led to the discovery of a ruptured right tubal pregnancy. The patient sued, claiming negligence in the failure to diagnose the ectopic pregnancy. An initial verdict against the defendant doctor was overturned on appeal, because the plaintiff's expert lacked sufficient qualifications. The expert had completed residencies in both orthopedics and psychiatry, but had never practiced obstetrics or gynecology and, indeed, had never cared for a pregnant patient.

Finally, successful suit can be brought for failure to accurately calculate gestational age. In an Alabama case, a woman stopped taking oral contraceptive medication in late January and, when she suspected pregnancy, visited her physician in March.[3] He estimated that conception had occurred in December although she was on contraceptive medication at that time. Based on his calculations, the physician induced labor the following October. A five pound, nine ounce infant was born with respiratory distress syndrome. The child was placed on a respirator, a pneumothorax developed, and insertion of a chest tube was required.

The parents sued, alleging a negligent calculation of gestational age that resulted in injury to the premature infant. The plaintiff's expert criticized the defendant doctor for not having employed sonography to confirm his calculated gestational age. A trial verdict for the plaintiffs was affirmed on appeal.

Despite recent technological advances, both provider oversight and the vagaries of clinical medicine still lead to failures in diagnosing and staging pregnancy. A high index of suspicion and proper utilization of diagnostic tests remain crucial in limiting liability.

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ANSWERS TO CME QUESTIONS

1.	**A**	**11.**	**C**
2.	**C**	**12.**	**B**
3.	**D**	**13.**	**D**
4.	**E**	**14.**	**E**
5.	**E**	**15.**	**D**
6.	**D**	**16.**	**C**
7.	**D**	**17.**	**D**
8.	**C**	**18.**	**C**
9.	**D**	**19.**	**E**
10.	**D**	**20.**	**C**

DEPARTMENT OF VETERANS AFFAIRS ANALYSIS OF MEDICAL MALPRACTICE CLAIMS FY 1993 REPORT

by Richard L. Granville, M.D., J.D., Galen Barbour, M.D., Jay Halpern, M.A., Michael Greenblatt, M.P.A., Patricia Murray, R.N., M.S., COL Frank T. Flannery, MC, USA, Donald Fournier, B.S., M.A., James Fitzsimmons, R.N., B.S.N., and Douglas Bradshaw, J.D.

INTRODUCTION

In 1992, the Office of the Associate Chief Medical Director for Quality Management of the Department of Veterans Affairs (VA) and the Armed Forces Institute of Pathology (AFIP) entered into a sharing agreement to assist efforts aimed at improving the quality of VA medical care. Shortly thereafter, the Department of Legal Medicine, AFIP, began collecting VA medical malpractice claims data and extracting information for analysis from medical records and associated documents. The sharing agreement pertains to all malpractice claims involving medical care rendered by the VA that were filed administratively since 1 October 1992. An existing malpractice data collecting system, the Tort Claim Information System (TCIS), was substantially modified by the agreement. The modified TCIS was described in a previous issue of this publication.[1]

The first annual report of aggregate data, based on claims filed between 1 October 1992 and 30 September 1993, was produced by the Department of Legal Medicine six months after the period ended.[2] Copies of the report were sent to the VA Central Office, the four VA regions and to the Office of Quality Management of each VA medical facility. During the 1993 fiscal year, 801 medical malpractice claims were filed against the Department of Veterans Affairs. The VA had approximately 925,000 hospital discharges and 26,000,000 outpatient visits during the same time period. The rate of claims per hospital discharge was less than one per 1,000 hospital patient discharges (.864/1000).

Both this review and the 1993 report are based on newly filed claims alleging medical negligence. The merits of the allegations are often not determined until cases are nearly resolved. According to the Office of the General Counsel, VA, the average time between the date of an incident and the date of case closure (both administratively closed cases and those closed by litigation) is 3.6 years. Closure information on most cases, therefore, is not available and must be addressed in future reports.

Over 200 separate data elements can be collected on every medical malpractice claim, and these elements are collected at various stages in the TCIS. The TCIS data elements entered by the Office of the District Counsel contain legally related material with some limited clinical information. The Provider Information and Peer Review Form includes information concerning components of care reviewed by a physician or other appropriate health care practitioner from the facility where the alleged negligence occurred, as well as an overall assessment of the quality of the care rendered. The AFIP Data Collection Form consists of clinical data elements that are collected from medical records and associated documents.

MEDICAL MALPRACTICE DATA

The compliance rate among the Offices of the District Counsel in reporting the initial TCIS data on newly filed malpractice claims was high. Of 801 claims filed during fiscal year 1993, the Department of Legal Medicine had received approximately 752 TCIS printouts and copies of claim forms by 1 January 1994, the cutoff date for submission of case information for the 1993 report. Of those claims for which TCIS printouts were received, 83 percent were open, with the remainder settled, denied or closed through litigation by the cutoff date.

The response by the facilities and the four VA regional offices has been similarly excellent. Monthly status reports that apprise the four regions about overdue Peer Review Forms and medical records were initiated early. By the 1993 report cutoff date, Peer Review Forms and medical records were received on 653 cases, and AFIP reviews were completed on 501.

The figures and tables that follow display different "n" values reflecting their different sources. Figures 1 and 2 and Tables 1 through 4 were produced from TCIS forms. Figure 3 and Table 5 are based on data from Provider Information and Peer Review Forms. Tables 6 and 7 convey information from AFIP reviews.

Figure 1 is an analysis of the severity of injury resulting from the alleged malpractice. The notion that most VA medical malpractice claims concern frivolous matters appears refuted by this data. In over 80 percent of the claims, the injury was reported as either of major severity or resulting in death.

Figure 2 provides a breakdown of cases by the Injury Coding System used in the TCIS. More than half the cases were either surgery

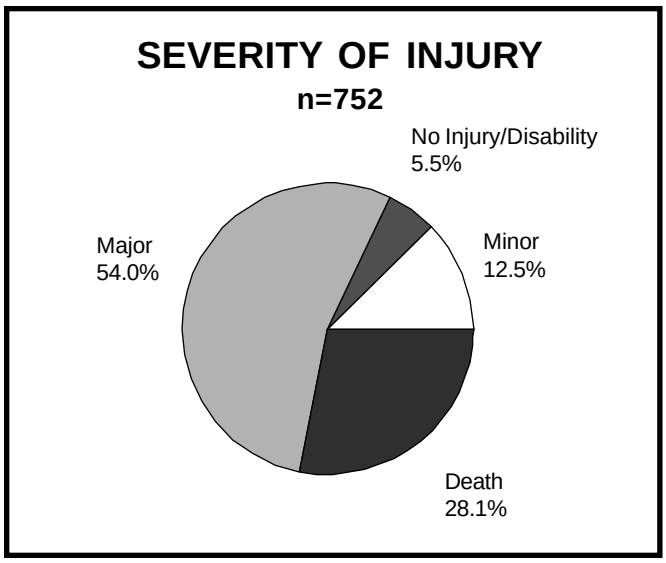


FIGURE 1

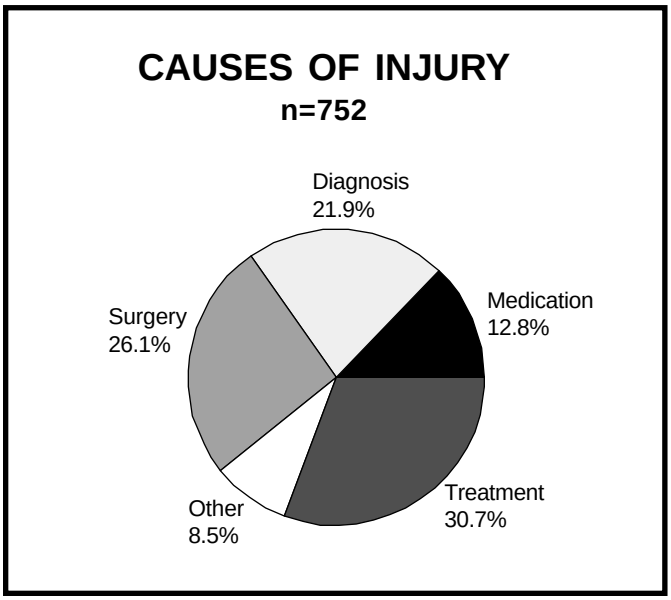
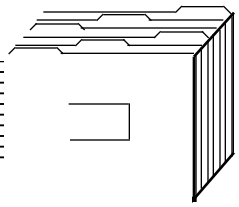


FIGURE 2



CLINICAL SPECIALTY
n=997

Specialty	Frequency	Percentage
Internal Medicine	131	13.4%
General Surgery	87	8.9%
Psychiatry	74	7.8%
Orthopedic Surgery	67	6.9%
Nursing	54	5.6%
Emergency Medicine	53	5.6%
Cardiology	53	5.6%
Gastroenterology	34	3.6%
Radiology	33	3.5%
Cardiothoracic Surgery	28	2.9%

TABLE 1

or treatment related, 26.1 percent and 30.7 percent, respectively. Medication related cases accounted for 12.8 percent of the injuries.

The ten most commonly involved clinical specialties are listed in Table 1. Since three clinical specialties can be listed for each malpractice claim, a total of 997 specialties were listed for the 752 claims in the TCIS database. The most frequently reported specialty was internal medicine with 131 cases or 13.1 percent. Other frequently listed specialties were as follows: general surgery, 8.7 percent; psychiatry, 7.4 percent; orthopedic surgery, 6.7 percent; and nursing, 5.4 percent.

This data can be compared with that from the private sector. A 1984 study by the General Accounting Office contained information from the civilian sector regarding 71,930 malpractice claims closed by 25 insurers.[3] The most frequently represented physician specialty was obstetrics/gynecology with 8,927, or 12.4 percent of claims. Other frequently represented specialties in this study were: general surgery, 12.1 percent; orthopedic surgery, 8.4 percent; internal medicine, 7.5 percent, general practice, 6.3 percent; family practice, 6.3 percent; and radiology, 5.5 percent. Comparisons between VA and civilian specialty data undoubtedly reflect their patient populations. The VA has little or no obstetrics and, therefore, has no claims involving this specialty. As an aside, obstetricians are usually "over represented" in claims data, i.e., the rate of claims per 100 obstetricians is higher than that for most physicians. On the other hand, internal medicine and psychiatry are especially busy clinical areas within the VA medical care system, and the percentage of claims involving these two specialties reflect this.

CATEGORY OF NEGLIGENCE
n=1276

Category	Frequency	Percentage
Treatment Related	357	30.1%
Surgery Related	268	21.1%
Diagnosis Related	215	23.2%
Medication Related	166	13.0%
Monitoring	53	4.1%
Risk Management	47	3.6%
Miscellaneous	44	3.4%
I.V./Blood Product	23	1.8%
Biomedical Equipment	13	1.0%
Anesthesia Related	10	.7%

TABLE 2

Table 2 provides a general breakdown of the allegations of negligence in the database. Three categories of alleged negligence can be recorded for each malpractice claim. A total of 1,276 allegations of negligence were entered for 752 claims. Treatment related cases, the most frequent category of alleged negligence, comprised 30 percent of the negligence codes. Diagnosis related cases accounted for 23.2 percent and surgery related cases accounted for 21.1 percent. These percentages are similar to recent data reported by the St. Paul Fire and Marine Insurance Company. In the insurer's 1992 report, 28 percent of 7,319 malpractice cases

reported during 1990 and 1991 involved the failure to diagnose, 26.3 percent involved improper treatment, and 26 percent involved surgery.[4]

Medication related errors in the VA database accounted for 166 negligence claims or 13 percent of the total. In June 1993, the Physician Insurers Association of America (PIAA) released a study on medication error as a cause of professional negligence claims. This study was based on the PIAA Data Sharing Project for which twenty of the forty-one member companies combined their malpractice claim experiences. Of the 90,166 claims included in their database, 6,646, or 13.56 percent, involved a medication related error.[5] The PIAA study also noted that these errors were particularly injurious and expensive, yet often involved avoidable mistakes. As the TCIS grows, medication errors will be an important area to scrutinize.

HOSPITAL SERVICE
n=752

Service	Frequency	Percentage
Medical	234	31.1%
Surgical	209	27.8%
Ambulatory Care - OPD & Emergency	86	11.6%
Psychiatry	57	7.5%
Nursing	27	3.7%
Other	139	18.3%

TABLE 3

Table 3 lists the most frequently represented hospital services. Up to three hospital services can be recorded for each occurrence in the database, but this table displays the hospital service that was first recorded. Medical and surgical services, with 31.1 percent and 27.8 percent, respectively, were the most frequently represented hospital services in the database.

LOCATION OF INJURY
n=752

Location	Frequency	Percentage
Operating Suite	179	23.9%
Patient's Room	177	23.6%
Outpatient Area	130	17.3%
Emergency Room/ Admitting Area	53	7.0%
Special Procedure Room	27	3.6%
Radiology	23	3.0%
Intensive Care	19	2.5%
On VA Grounds	9	1.1%
Recovery	8	1.0%
Rehabilitation Clinic	7	.9%
Other	120	16.1%

TABLE 4

Table 4 provides a breakdown of the location of the injury for the 752 cases. In nearly half, the injury occurred either in the patient's room or in the operating suite. In another 17 percent, the injury occurred in the outpatient area.

A determination concerning the standard of care is made by a reviewer at the medical treatment facility and recorded on the Provider Information and Peer Review Form. The standard of care is graded Level 1, 2, or 3. A Level 1 standard of care indicates that *most experienced, competent practitioners would have handled the case similarly in all respects*. A Level 2 grade indicates that *most experienced, competent practitioners might have handled the case differently in one or more respects*. A Level 3 grade indicates that *most experienced, competent practitioners would have handled the case differently in one or more respects*. Figure 3 indicates that in 68.5 percent of cases, the care was determined to be Level 1, in 21.5 percent, Level 2, and in 10 percent, Level 3. This is similar to standard of care determinations by senior peer reviewers in the DoD system.

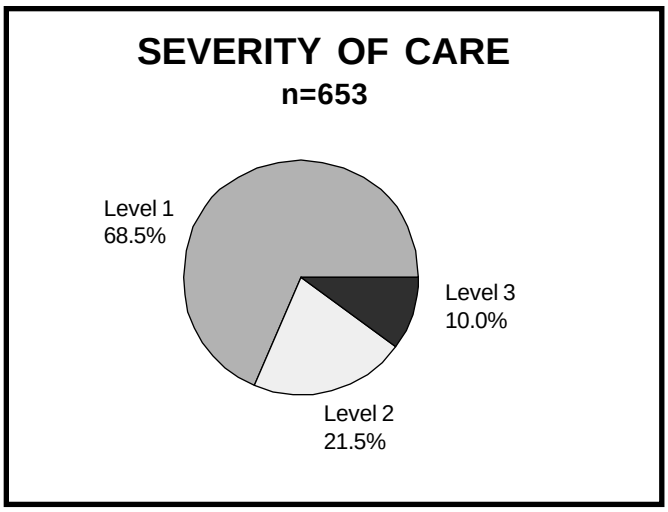


FIGURE 3

Approximately 65 percent of DoD malpractice claims are determined to involve acceptable medical care, 30 percent involve substandard care, and 5 percent are indeterminate regarding the quality of care rendered.[6]

POSITION OF INVOLVED PROVIDER
n=1321

Position	Frequency	Percentage
Staff Physician	809	61.3%
Physician in Training	433	32.8%
Nurses	44	3.3%
PA	13	.9%
Dentist	7	.5%
Technicians	6	.4%
Pharmacist	5	.3%
Therapist	3	.2%
Administrative Officer	1	.1%

TABLE 5

Table 5 provides a breakdown of claims based on the role played by the provider in rendering care. A total of 1,321 providers were named in 653 cases of alleged medical malpractice. Staff physicians comprised 61 percent; physicians in training, 32.8 percent.

Table 6 is a list of the nine most frequently occurring presenting symptoms in the database. A total of 1,048 presenting symptoms were identified in 501 malpractice cases reviewed by the AFIP. The most frequent presenting symptoms

PRESENTING SYMPTOM
n=1048

Symptom	Frequency	Percentage
Chest Pain	48	4.9%
Joint Pain or Stiffness	41	3.9%
Abdominal Pain	38	3.6%
General Weakness	37	3.5%
Dyspnea	34	3.2%
Backache	29	2.8%
Depression	27	2.6%
Substance Abuse	23	2.2%
Local Weakness	20	1.9%

TABLE 6

were: chest pain, 48 cases; joint pain or stiffness, 41 cases; abdominal pain, 38 cases; and general weakness, 37 cases. Interestingly, one common and potentially dangerous presenting symptom, headache, did not make the list.

Table 7 (next page) lists the organ system involved for 501 cases in the database. The two most frequently involved were the circulatory system with 90 cases, and the musculoskeletal system with 85 cases.

ORGAN SYSTEM INVOLVED
n=501

Organ System	Frequency	Percentage
Circulatory System	90	18.0%
Musculoskeletal System	85	17.0%
Digestive System	54	10.8%
Nervous System	44	8.8%
Mental Disorders	44	8.8%
Other	184	36.6%

TABLE 7

NEW DEVELOPMENTS AND PLANS FOR TCIS

The TCIS will continue to be a vital component of VA Quality Management efforts. Health care providers and administrators, as well as Congress, have demonstrated recurring interest in data regarding medical malpractice claims. The system will continue to evolve, and future reports will contain more information related to closed cases. Comparison of fiscal year data with that from prior years will also be possible.

Some changes in the TCIS, Provider Information and Peer Review, and AFIP Data Collection Forms are being considered to better facilitate data collection. Due to ongoing changes in the VA Health Care System, information flow for the TCIS will have to be modified to ensure continued success of the program.

Finally, as new trends in medical malpractice are recognized in this database, such as those involving certain diagnoses, procedures or specialties of medicine, researchers are encouraged to contact the Office of Quality Management, VA, or the Department of Legal Medicine, AFIP, to arrange specific studies. Focused studies concerning cardiology/cardiothoracic surgery, anesthesiology and medication related errors are currently being developed.

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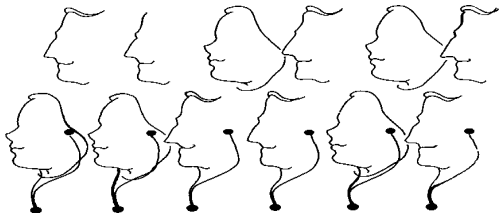


CONTINUING MEDICAL EDUCATION QUIZ

INSTRUCTIONS TO EARN 5 CME CREDIT HOURS

Print the answer sheet on the back page. Answer all 20 questions below. Each question has only one correct answer. An answer key is provided on page 42.

- QUESTIONS -

1. In *Tarasoff*, the court followed a common law principle that volunteers:
   A. must exercise due care.
   B. may commit negligent acts.
   C. have no legal obligations.
   D. should reduce their duties to writing before the fact.
   E. must never be involved in an adverse out come.

2. The duty to warn, as enunciated in *Tarasoff*, involves:
   A. only those within the doctor-patient relation ship.
   B. residents of specified geographical areas.
   C. threatened persons in foreseeable danger.
   D. only health care providers.
   E. only law enforcement personnel.

3. The difficulties in fulfilling the duty to warn include:
   A. predicting violent behavior.
   B. identifying potential victims.
   C. maintaining the confidentiality of physician-patient relationships.
   D. all of the above.
   E. none of the above.

4. Legislation on the duty of mental health providers to warn third parties about behaviorally dangerous patients:
   A. is unconstitutional.
   B. has been enacted in most states.
   C. never applies to non-physicians.
   D. applies only to psychiatrists.
   E. none of the above.

5. Medical records provide:
   A. communication between health care professionals.
   B. documentation of patient care.
   C. a basis for clinical outcome assessment.
   D. evidence in medical malpractice suits.
   E. all of the above.

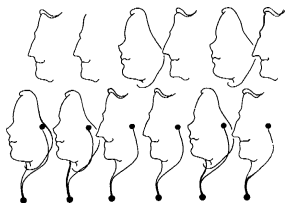
6. Altering the medical record following an allegation of medical negligence is a:
   A. respected risk management tool.
   B. justified response by a provider to a patient who has retained legal counsel.
   C. reasonable maneuver when the risk of discovery is small.
   D. foolhardy medicolegal risk.

7. The medical record should:
   A. support the diagnosis.
   B. outline treatment and management.
   C. describe the patient's response to treatment.
   D. all of the above.

8. Inappropriate medical record entries include:
   A. changes in diagnosis or impression.
   B. a description of complications encountered in performing a procedure.
   C. personal comments regarding other health care providers.
   D. data on patient progress.

9. Negligence in cases involving the misdiagnosis of pregnancy may result from:
   A. failing to order appropriate tests.
   B. prescribing potentially teratogenic medications.
   C. calculating gestational age inaccurately.
   D. all of the above.

10. Regarding medical malpractice claims filed against the Department of Veterans Affairs in 1993, what is **FALSE?**
    A. Anesthesia related claims represent less than one percent of the total.
    B. A large majority involve death or major injury.
    C. Nearly half involve care rendered in the patient's room or the operating suite.
    D. The most commonly involved specialty is psychiatry.



CONTINUING MEDICAL EDUCATION QUIZ, cont'd

11. Regarding those claims, what is **TRUE**?
    A. Physicians in training were involved in a large majority.
    B. The most common presenting complaint was chest pain.
    C. Approximately one in eight involved medica tions.
    D. The most commonly involved specialty is neurosurgery.

12. The most important information to obtain and document during an eye examination concerns:
    A. pupil reactivity.
    B. visual acuity.
    C. corneal clarity.
    D. extraocular motility.
    E. intraocular pressure.

13. Immediate ophthalmology consultation is obligatory for:
    A. hyphema.
    B. intraocular foreign bodies.
    C. penetrating injury of the globe.
    D. all of the above.
    E. none of the above.

14. Eye examinations must be deferred in:
    A. bedridden patients.
    B. illiterates.
    C. children.
    D. all of the above.
    E. none of the above.

15. Regarding pediatric bacterial meningitis:
    A. The provider must listen to parents carefully.
    B. Primary care providers should pursue appropriate consultation with specialists.
    C. The key to clinical success is considering the possibility of meningitis in any febrile child.
    D. All of the above.
    E. None of the above.

16. All of the following criteria have been proposed to identify infants less likely to suffer serious bacterial infections **EXCEPT**:
    A. The infant appears well.
    B. The infant has been previously healthy.
    C. The infant was born in a teaching hospital.
    D. No source of infection is identified.
    E. Lab studies are normal.

17. Regarding pediatric bacterial meningitis, the following statement is **FALSE**:
    A. Medical malpractice claims involving treatable meningitis can be unusually expensive.
    B. The functional status of the patient's immune system is a key variable in determining the clinical presentation.
    C. Irritable lethargy is a more sensitive indicator of infection than nuchal rigidity, headache, and vomiting.
    D. Clinical response to antibiotics is uniformly excellent.

18. Regarding laparoscopic cholecystectomies, the following statement is **FALSE**:
    A. They are more commonly performed in the U.S. today than open cholecystectomies.
    B. They result in less patient pain, shorter hospital stays and shorter periods of postoperative convalescence than open cholecystectomies.
    C. Their complication rate increases proportionately to the surgical experience with them.
    D. The lack of sensory input traditionally available during abdominal surgery contributes to a steep "learning curve" for a surgeon who begins performing them.

19. The PIAA study on laparoscopic surgery claims found that:
    A. slightly more than half the claims involved laparoscopic cholecystectomy (LC).
    B. in three quarters of the LC claims, the patient injury was not recognized at the time of initial surgery.
    C. LC claims were less likely to be paid than companion PIAA claims involving open cholecystectomy.
    D. All of the above.
    E. A and B only.

20. All of the following allegations will likely be made in future professional negligence cases involving laparoscopic cholecystectomy **EXCEPT**:
    A. The surgeon was improperly trained.
    B. The surgeon was improperly credentialed.
    C. The procedure was improperly approved by the Food and Drug Administration.
    D. The surgery was improperly performed.
    E. The patient consent was improperly informed.

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